



HHS **Open** Government Plan

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Executive Summary

What is “Open Government?”

An Open Government is one that is transparent, publishing government data that generates significant benefit for citizens and which helps the public hold the government accountable. An Open Government embraces the notion of public participation in the work of government. And it's one that is effective at encouraging collaboration across the government and with the world outside government. Above all, an Open Government is one that works better -- one that leverages the principles of transparency, participation, and collaboration to deliver better results to the American people.

This Open Government Plan represents the official response of the U.S. Department of Health and Human Services (HHS) to the White House's Open Government Directive, issued on December 8, 2009.

The plan embraces the idea of working proactively and energetically to advance a culture of Open Government at HHS. We have created an Open Government Steering Group, designated senior accountable officials for Open Government, and formally charged our department-wide Data Council, Chief Information Officer Council, and Innovation Council with a range of Open Government responsibilities. Through these bodies, we will help catalyze Open Government action across HHS, supporting the work of leaders and innovators to advance Open Government at every level through education, communication, and processes that will encourage, share and celebrate best practices, including a new Secretary's Innovation Awards program.

We believe that transparency and data sharing are of fundamental importance to our ability to achieve HHS's strategic goals of advancing the health and well-being of the United States. HHS's vast stores of data are a remarkable national resource which can be utilized to help citizens understand what we do and hold us accountable, help the public hold the private sector accountable, increase awareness of health and human services issues, generate insights into how to improve health and well-being, spark public and private sector innovation and action, and provide the basis for new products and services that can benefit the American people. Our plan describes exciting new developments regarding how we will leverage HHS data to accomplish these objectives:

- A multi-faceted new transparency push by the Centers for Medicare and Medicaid Services (CMS) in 2010 -- including the following:
 - A new interactive “CMS Dashboard,” debuting in beta mode with the launch of this Open Government Plan, which allows the public to visualize and analyze Medicare spending with unprecedented ease and clarity – starting with inpatient hospital spending. You can visit the Dashboard at <http://www.cms.gov/Dashboard/>
 - Creation of 9 Medicare claim “basic files,” one for each major category of health care service, to be released from September to December 2010 for free public download on Data.gov. These files will contain a limited number of variables and be de-identified and configured through a rigorous process, in close consultation



with privacy experts, re-identification experts, researchers, and key stakeholders, to ensure the protection of beneficiary privacy and confidentiality

- A significantly improved user interface and analytical tool for viewing existing CMS COMPARE data on quality performance of hospitals, nursing homes, home health agencies, and dialysis centers. This interface and tool is debuting at data.medicare.gov with the launch of this Open Government Plan.
- Online publication of detailed Medicaid State Plan documents and amendments on the CMS website by the end of 2010
- The release of new national, state, regional, and potentially county-level data on Medicare prevalence of disease, quality, costs, and service utilization, never previously published, as part of HHS's Community Health Data Initiative by the end of 2010
- A Transparency Initiative being pursued by the Food and Drug Administration (FDA), being formulated with extensive public input, and focused on (1) providing the public with information regarding how FDA works, (2) proactive disclosure of useful, non-proprietary information in the possession of the agency, and (3) ways in which FDA can become more transparent to regulated industry. FDA is also launching FDA-TRACK, a new agency-wide performance management system, which debuts in beta mode with the launch of this Open Government Plan. FDA-TRACK, when fully implemented, will allow the public to monitor over 300 performance measures and 80 key projects across 90+ FDA program offices on an ongoing basis
- Other new data sets and tools to be published from across HHS
- Implementation of a new process for the proactive identification, prioritization, publication, and monitoring of data releases – to be coordinated overall by HHS's Data Council. This process will include an "HHS Apps Challenge" – a public competition for the best applications built utilizing our data
- A major push to assess current HHS operations in support of the Freedom of Information Act (FOIA), identify and prioritize improvement opportunities, and define a roadmap to implement the improvements

HHS will protect the confidentiality of individually identifiable information in any public data releases, including publication of data sets on the web. Recognizing that the risks of disclosure of personal identifiable information mount as more and diverse data sets are released into the public domain, HHS will lead and support ongoing research into strategies to protect confidentiality while maintaining public access to data. As new approaches evolve, HHS will incorporate them into its data release policies. HHS is strongly committed to the protection of personal privacy and confidentiality as a fundamental principle governing the collection and use of data.

This plan also seeks to take Open Government to the next level by expanding opportunities for public participation in HHS activities and for collaboration across HHS and with the world outside HHS – especially via the use of new information and communications technologies.



Through a new HHS “Community of Practice” for Participation and Collaboration, Open Government innovators at HHS will be able to network with each other, share learnings and best practices, compile these best practices into an HHS “workplace menu” of participation and collaboration tools, compare the efficacy of different approaches, and work together on common issues. The Community of Practice will focus in particular on the advancement of innovative mechanisms for participation and collaboration at HHS – mechanisms that apply blogging, “crowdsourcing,” group collaboration, idea generation, mobile, and on-line challenge capabilities to key HHS activities:

- Delivery of consumer information on patient safety and health -- e.g., via FDA’s product safety text-message pilot, the Text4baby program, and use of social media to reduce harm from tobacco products
- User-friendly information services for health care delivery -- e.g., via work by the Agency for Healthcare Research and Quality to assess the effectiveness of cell phone applications as a health care program dissemination tool
- Medical research collaborations -- e.g., via the application of “crowdsourcing” and innovative patient engagement approaches to research on diabetes and women’s health issues
- Collaboration among HHS employees -- e.g., via work by the Office of the Assistant Secretary for Planning and Evaluation to research and pilot advanced collaboration tools
- Better health care through better information -- e.g., via the community-driven, highly collaborative “Nationwide Health Information Network – Direct” initiative being pursued by the Office of the National Coordinator for Health Information Technology
- Innovation in the workplace -- e.g., via the piloting of an online employee idea-generation tool and challenge program by the Centers for Medicare and Medicaid Services

Finally, we have designated five initiatives in particular as “Flagship Initiatives” that we believe embody the direction in which we are taking Open Government at HHS: the Centers for Medicare and Medicaid (CMS) Dashboard, the Food and Drug Administration’s (FDA) Transparency Initiative, FDA-TRACK, our push for FOIA Excellence, and the Community Health Data Initiative. The first four have been mentioned above. The fifth, the Community Health Data Initiative, is a major new public-private effort whose goal is help Americans understand health and health care performance in their communities relative to others – and to help spark and facilitate action to improve performance. As a core enabler of this initiative, HHS will be providing to the public, free of charge and any intellectual property constraint, a large-scale Community Health Data Set harvested from across HHS – a wealth of easily accessible, downloadable data on public health and health care performance across communities, including a major contribution of Medicare-related data from CMS (i.e., prevalence of disease, quality, cost, and service utilization data at the national, state, regional, and potentially county levels). The initiative is simultaneously working with a growing array of technology companies, researchers, health advocates, consumer advocates, employers, providers, media, etc. to identify and deploy uses of the data that would be most effective at (1) raising awareness of community health performance, (2) increasing pressure on decision makers to improve performance, and (3) helping to facilitate and inform improvement efforts. Such applications



and programs could include interactive health maps, competitions, social networking games that educate people about community health, enhanced web search results for health searches, etc. By leveraging the power of transparency, participation, and collaboration, the Community Health Data Initiative seeks to help significantly improve the health of our communities.

We at HHS are very excited about our path forward on Open Government. We view transparency, participation, and collaboration as vital enablers of maximum success in our mission to improve the health and welfare of the United States.

We see this Open Government Plan as just the beginning of our journey toward a more open and effective HHS. It's a plan and course of action that we will continue to update over time as we seek to change how HHS operates for the better. And it's a plan that will evolve in significant ways to encompass how we'll be applying the principles of transparency, participation, and collaboration to the historic work of implementing health insurance reform.

Any and all input you can provide is more than welcome – it's essential to our ability to advance openness at HHS and do the best job we can for the American people. To provide feedback on our plan, please visit us at our Open Government website, www.hhs.gov/open, where our plan will be posted for comment on an ongoing basis. Thank you very much for your thoughts and consideration.



1 - Introduction

What is “Open Government,” you may ask?

An Open Government is one that is “transparent.” In the words of President Barack Obama, it treats information maintained by the government as a “national asset” which should be disclosed rapidly, “in forms that the public can readily find and use,” while safeguarding privacy and national security. Government-supplied information can help citizens hold the public sector accountable by shining a light on government activity – whether it be detailed government spending information, the progress of key government projects, or White House visitor logs. Government data can help citizens hold the private sector accountable by providing information on private sector behavior -- such as emissions of harmful chemicals, which led to public scrutiny that drove companies to reduce these emissions by 40% over a 14-year period. Government data can spur the creation of new services that benefit the public, like new websites that enable people to track flight delays and restaurant health inspection scores – websites which sprung up rapidly after government data on these subjects was posted online. Government-supplied data can even spur the development of entire new sectors of activity, as happened with the release of government weather data (virtually all weather data comes from the government) and Global Positioning System (GPS) satellite navigation data.

An Open Government is one that is “participatory.” It is one that recognizes that a government that is disconnected from the people is one that will become increasingly ineffective over time at serving the needs of the people. It’s a government that seeks to tap into the experiences, ideas, and expertise of people across the country. In the words of the President, “Knowledge is widely dispersed in society, and public officials benefit from having access to that dispersed knowledge” – to help them stay abreast of issues facing citizens, formulate the right regulations and policies, and execute the work of government programs in a way that produces maximum benefit for the public.

An Open Government is one that is “collaborative.” It’s one that recognizes that in order to meet the challenges of the 21st century, teamwork is the order of the day. President Obama: “Collaboration actively engages Americans in the work of their government. Executive departments and agencies should use innovative tools, methods, and systems to cooperate among themselves, across all levels of government, and with nonprofit organizations, businesses, and individuals in the private sector.”

Above all, an Open Government is one that works better – a government that harnesses the principles of transparency, participatory democracy, and collaboration to produce the best possible results for the American people.

On his first day in office, President Obama issued a call for increased openness in government (http://www.whitehouse.gov/the_press_office/Transparency_and_Open_Government). This led to the creation of the federal government’s Open Government Directive, issued by the White House on December 8, 2009 (http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-06.pdf), which, among other things, called upon each federal agency to formulate a plan for how it intended to increase and accelerate openness in its programs and operations.



This plan is the official response of the U.S. Department of Health and Human Services (HHS) to the Open Government Directive. As you will see, we think that Open Government is a big deal – one that will be of decisive help to us and the public as we pursue our mission of advancing the health and well-being of the United States.

As you'll see, we have proactively chosen to go significantly beyond the basic requirements of the Directive in our Open Government Plan. At the same time, we know that there is much more progress we can make on all Open Government fronts. In fact, we regard this plan merely as the beginning of a journey toward a more open HHS – and a more effective HHS. It's a plan and course of action that we will continue to update over time as we seek to evolve how HHS operates for the better. Any and all input you can provide is more than welcome – it's essential to our ability to advance openness at HHS and do the best job we can for the American people.

And in the spirit of Open Government and public input we've received on our new Open Government blog (www.hhs.gov/open), we have sought to write this document in plain English. We realize that government documents aren't always the easiest to understand. We have therefore resolved to lead by example by attempting to make this plan a jargon-free zone. Let us know if we've succeeded. If you can't understand a given section, let us know, and we'll do our best to revise it to make it more comprehensible.



2 - Leadership, Governance, and Culture Change

The Department of Health and Human Services (HHS) is the United States government's principal force for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. Comprising 27 agencies and offices, HHS administers over 330 programs with a total FY 2010 budget of \$840 billion. (For a leadership and organization chart of HHS, see www.hhs.gov/open).

In other words, HHS is a highly diverse, complex place -- bound together by the noblest of missions, but decidedly not uniform in culture, work, or work approach.

The acceleration of Open Government in such a department is a non-trivial exercise. It has required us to spend a fair amount of time thinking about issues of leadership, governance, and culture change as we craft how openness can and should advance at HHS.

2.1 - How We Developed Our Open Government Plan

How does one develop a coherent Open Government Plan in a place this big and diverse?

First, we decided that our approach needed to be interdisciplinary. The advancement of transparency, participation, and collaboration requires policy, legal, technology, public affairs, financial, and operations leadership. We therefore created an HHS Open Government Steering Group comprised of all of these disciplines, co-chaired by HHS's Chief Technology Officer and Assistant Secretary for Public Affairs, to oversee the formulation of our Open Government Plan.

Second, it was obvious that our approach needed to coordinate thinking and action across all of the many agencies and offices of HHS. We chose to make this happen by using established cross-HHS councils, with representation from all of our offices and divisions, and which were perfectly positioned to help advance key aspects of Open Government:

- The HHS Data Council and Chief Information Officer (CIO) Council, which focused on the transparency section of our plan
- The recently formed HHS Innovation Council, which formulated the participation and collaboration section of the plan

With the help of these Councils and key leaders across HHS's divisions, we identified an array of "open government innovators" across the department -- who are truly the folks taking the lead on advancing transparency, participation, and collaboration at HHS. It is these innovators who represent the heart and soul of the Open Government movement at HHS and whose energy and ideas inform and drive this plan.

Third, we felt like there was much to be gained from collaboration with our fellow departments across the federal government. We benefited greatly from participation in a government-wide Open Government Steering Committee convened by the White House and from a volunteer workgroup of agencies including HHS, the Department of Transportation, the Department of the Treasury, the Social Security Administration, the Department of Labor, the General Services Administration, the National Archives and Records Administration, and others, which hammered out a set of Open Government "leading practices" to help guide our thinking.



Finally, we felt that it was vital to gather public input regarding how we should shape our plan. On February 6, along with other federal departments, we debuted our HHS Open Government website – www.hhs.gov/open. Among other things, our website posted an outline of our plan and invited folks to share their ideas regarding how we could advance transparency, participation, and collaboration at HHS. We blogged about specific Open Government topics, posing questions to the public and responding to public input. And through our interagency volunteer workgroup focused on open government “leading practices,” we received significant input from Open Government advocates that did much to shape our plan.

2.2 - How Open Government Efforts Will Be Led at HHS

The mechanisms we set up and utilized to develop our Open Government Plan are the same ones we will utilize going forward to oversee execution of the plan and to evolve it going forward:

1. ***HHS Open Government Steering Group, operating under the authority of the Secretary of HHS and which will oversee Open Government efforts at HHS overall*** – including oversight of our work to execute on our obligations under the Freedom of Information Act (more on this later in the plan)
2. ***Data Council and the Chief Information Officer Council*** – which will coordinate data transparency efforts at HHS
3. ***Innovation Council*** – which will coordinate participation and collaboration efforts at HHS

These Councils will not attempt to manage Open Government via a “top-down,” “command-and-control” style. Rather, they will seek to help catalyze, coordinate, and network Open Government action across HHS, incubating and supporting the work of the “open government innovators” at every level and across every HHS division who are the trailblazers helping to create a more open HHS.

HHS’s Chief Technology Officer and Assistant Secretary for Public Affairs will be the department’s senior officials accountable for Open Government strategy and execution. Our Assistant Secretary for Financial Resources has been named the senior official accountable for the quality of financial data supplied by HHS. They will update the leadership of HHS on the status of Open Government work on an ongoing basis, including quarterly briefings for the Deputy Secretary and Secretary.

HHS will also continue to involve the public in the formulation of our Open Government work. We will continue to solicit feedback on our evolving Open Government Plan and blog on Open Government questions at www.hhs.gov/open. We look forward to continued consultation with Open Government experts on multiple fronts. We hope to grow the dialogue regarding Open Government at HHS over time into an ever richer one.



2.3 - How Open Government Supports Our Strategic Goals

HHS sees Open Government explicitly as a means by which HHS will become more successful in how well we deliver on our mission of improving the health and well-being of the United States.

The Open Government Plan directly supports the major work of the Department, including its highest priority activities and high priority performance goals. These include:

- Transformation of health care
- Prevention and wellness
- Early childhood health and development
- Protection of Americans in public health emergencies
- Pursuit and acceleration of scientific advances that benefit patient care
- Improvement of our food safety system

In addition, the concept of Open Government is being incorporated into HHS's Strategic Plan 2010-2015, which is currently under development. Once the new strategic plan's goals and objectives have been identified, they will inform proposals for new transparency, participation, and collaboration initiatives.

The central objective of Open Government at HHS is to advance the ability of the department to deliver on its mission through the power of transparency, participation, and collaboration. Optimizing how well we disseminate vital government information to the public, foster the use of that information, and engage citizens, health care providers, human service providers, non-profit organizations, businesses, state, local, and tribal governments, researchers, the media, advocacy organizations, and others outside HHS in the work of advancing these goals will be vital to achieving them. In fact, it's hard to imagine how we'll achieve maximum success with respect to our goals without doing so.

2.4 - How We Will Support Our Employees in the Pursuit of Open Government

Indeed, we believe that ramping up transparency, participation, and collaboration is so fundamental to our ability to execute on HHS's mission that it is important to develop organizational capabilities which will stimulate and support employee execution of Open Government activities at all levels of the organization. We plan to execute the following actions in 2010 along these lines:

1. Adapt our core strategic planning, IT planning, and budgeting processes to emphasize proactive data sharing. (For more details, see the Transparency section 3, page 12)
2. Establish a central location on the HHS intranet ("Open Government at HHS") that enables employees to find relevant Open Government information (i.e., policies,



standards, tools, training, etc.) easily. Publicize the availability of training and workshops provided by the department, the General Services Administration, and other organizations on Open Government topics

3. Develop a “Participation and Collaboration Resource Menu” for HHS employees, which will lay out methodologies, policies, tools, and best practices which can be used by employees seeking to engage the public and collaborate with others across and outside the government. (For more details, see the Participation and Collaboration section 4, page 46)
4. Launch a “Participation and Collaboration Community of Practice” at HHS which will enable HHS innovators to network with each other, learn together, and share best practices on this key Open Government topic. (For more details, see the Participation and Collaboration section 4, page 46)
5. Launch a new Secretary’s Innovation Awards program, which will recognize and reward extraordinary achievements by employees who innovate how HHS operates in ways that advance our mission. The program will recognize its first award recipients in July of this year, with two award cycles annually after that. Employees who demonstrate powerful ways to harness the power of transparency, participation, and collaboration to improve the results delivered by HHS will be leading candidates for Innovation Awards on an ongoing basis. Nominations will be submitted online across the department, displayed for online voting, and publicized as an ongoing “Innovation Gallery” across HHS. It is our belief that one of the most effective ways to evolve the culture of HHS toward more and more Open Government is to celebrate “Open Government entrepreneurs” and demonstrate that Open Government innovation is a way to advance one’s brand and career at HHS
6. Engage in an HHS-wide Open Government communication plan – including Open Government “town hall” meetings across the department

2.5 - How We Will Measure the Success of Open Government at HHS

We anticipate a progression over time in how we measure the success of Open Government at HHS.

Initially, that measurement will be qualitative – i.e., how well we execute on this plan. We will report progress with respect to execution of the plan to the public on our Open Government website (www.hhs.gov/open) on a quarterly basis, in the “Evaluating Our Progress” area.

One of our key tasks is to develop the right quantitative metrics for the success of Open Government at HHS. Our current metrics are relatively basic:

Transparency:

- Number of high value data sets and tools published
- Freedom of Information Act (FOIA) backlog, time to respond, and total requests processed



Participation and Collaboration:

- Number of opportunities for the public to provide input into the work of the department
- Number of HHS public-private collaborations

These metrics will need to be refined and others added via a cross-HHS dialogue as our work progresses. We will also look to the public to help us define relevant measures. As described subsequently in the Participation and Collaboration section of the plan, we will be developing standard metrics for measuring the success of efforts to engage the public. These metrics will go beyond volume of participation (e.g., number of comments received) to the impact of participation (e.g., number of ideas from the public that are adopted and what impact they have on results delivered by the agency).

This points to the ultimate destination of our journey to measure the success of Open Government at HHS: its impact on the results produced by HHS. As we have said previously, the central objective of Open Government at HHS is to enable the department to deliver better on its mission of advancing the health and well-being of the nation. The ultimate measure of success of Open Government should be improvement in the fundamental efficiency and effectiveness of HHS. In our quarterly reports on our Open Government execution, we will describe the qualitative and quantitative impact that Open Government is having on HHS performance, as part of an ongoing evaluation of the effectiveness of our Open Government programs and policies.

2.6 - How We Will Seek to Collaborate with Other Agencies on Open Government Efforts

We believe that it will continue to be vital to collaborate with other agencies in the advancement of Open Government across the government. We plan to do so in several ways:

- Continued leadership of and participation in the volunteer interagency workgroup on Open Government “leading practices”
- Sharing of the “Participation and Collaboration Resource Menu” we will be developing with other agencies
- Continued leadership of and support for an intergovernmental community of practice on “ideation tools” – tools that can help agencies gather and process ideas from employees and the public. Currently, over 30 federal agencies participate in this forum, which meets monthly and also communicates via an intergovernmental portal
- Leadership of an “Open Government for Health” interagency group (launched on March 2) on how agencies can coordinate or integrate complementary data for public release
- Naming of an HHS advocate for Open Government who can get the word out about what HHS is doing on Open Government and is available to talk with other agencies about what HHS has learned. This advocate will initially be Todd Park, HHS Chief Technology Officer and one of the senior accountable officials for Open Government
- Sharing of all materials, results, tools, and training that could be transferable to other agencies with the government-wide Open Government Steering Committee



3 - Transparency

We believe that transparency and data sharing are of fundamental importance to our ability to achieve HHS's strategic goals of advancing the health and well-being of the United States. HHS's vast stores of data are a remarkable national resource which can be utilized to help citizens understand what we do and hold us accountable, help the public hold the private sector accountable, increase awareness of health and human services issues, generate insights into how to improve health and well-being, mobilize public and private sector action and innovation to improve performance, and provide the basis for new products and services that can benefit the American people.

What follows is a plan that will significantly ramp up how we leverage HHS data to accomplish these objectives. It's a plan that revolves around four core principles:

1. Publish more government information online in ways that are easily accessible and usable
2. Develop and disseminate accurate, high quality, and timely information
3. Foster the public's use of the information we provide
4. Advance a culture of data sharing at HHS

3.1 - HHS Data Currently Available for Download

HHS has already posted 117 data sets and tools on Data.Gov since its debut in May 2009. Check out the inventory of them on our Open Government website (www.hhs.gov/open) or at www.data.gov. These data sets and tools include:

- Hospital-by-hospital quality performance statistics compiled by the Centers for Medicare and Medicaid Services (CMS) and which can help inform consumer choices regarding where to get care. Also available: similar information on nursing homes, dialysis facilities, home health agencies
- A regularly updated data set representing all technologies available for licensing from the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), helpful to entrepreneurs and companies looking to drive innovation
- A household cleaning products data set that links over 4,000 consumer brands to health effects as submitted by manufacturers and which allows scientists and consumers to research products based on chemical ingredients
- Detailed summaries of Medicare expenditures on physician services, which allow the public to understand patterns of Medicare spending and analyze the types of services being delivered to address the health needs of the Medicare population. (This data set was first added on January 22 as one of HHS's new "high value" data sets under the Open Government Directive)



- CDC WONDER, which provides access to online databases, reports, references, and links to external data systems containing a wide range of highly valuable public health information. Data sets that can be queried online from WONDER are continually updated and include data sets related to Acquired Immune Deficiency Syndrome (from 1981), births (starting in 1995), cancer registry statistics (beginning in 1999), mortality data (1979-2006), population estimates (beginning in 1970), sexually transmitted disease (STD) morbidity (1984-2008), tuberculosis case reports (1993-2007), and vaccine adverse events reports (1990-2010). CDC WONDER currently hosts 42 searchable online databases, holding over 200 gigabytes of data. In addition, CDC WONDER allows access to reports, statistics, standard reference tables, and historical guidelines. The wonder.cdc.gov website services over 47 million requests a year. CDC WONDER is widely used by public health programs, researchers, and schools of public health curricula. CDC WONDER has over 1000 citations as a data source for scientific papers and articles
- A downloadable data set which lists all NIH-funded research grants, contracts, and intramural projects from 2005-2009, abstracts for these projects, citation information for publications that acknowledged support from any of these projects, and patents reported by investigators funded by these NIH projects. This data set was published on January 22 as one of HHS's new "high value" data sets under the Open Government Directive. NIH had received many public requests for this information to be made available in downloadable form. Patient advocates are enthusiastic about this dataset because it makes information available on grants and publications that they had been amassing manually. The biomedical research community is interested in analyzing the data to find collaborators, develop literature bases, and analyze trends in biomedical research. Policy makers and evaluators are interested in analyzing research funding, programs supported, and the results of those programs. Venture capitalists and pharmaceutical companies are interested in analyzing the files to understand the latest trends in federally-funded research
- And much more

3.2 - New High-Value Data Sets and Tools

"High value" is defined by the Open Government Directive as information which can be used to increase agency accountability and responsiveness, improve public knowledge of the agency and its operations, further the core mission of the agency, create economic opportunity, or respond to need and demand as identified through public consultation. As described earlier, the Chief Information Officer Council and Data Council at HHS have executed an initial review of the current inventory of HHS data to see what additional high value data can be released. A directory of major HHS data and statistical systems is available at http://www.hhs-stat.net/scripts/meta_des_new_17.cfm and is continually updated, and an inventory of Office of Management and Budget-approved data collection projects is available at <http://www.reginfo.gov/public/do/PRAMain>.

As a result of this initial portfolio review, HHS has decided to release 14 new high-value data sets and three new high-value tools on Data.gov by the end of 2010. Of the 14 new high-value



data sets, 12 have never previously been available to the public in any form -- 10 data sets from the Centers for Medicare and Medicaid Services (CMS) alone. (The other two data sets are either online for the first time or downloadable in open format for the first time). The three tools – the CMS Dashboard, FDA-TRACK, and the Office of the National Coordinator for Health Information Technology's Dashboard – will be brand new.

In addition to these 17 new data sets and tools, HHS will be posting more than 40 existing data sets and tools to Data.gov by the end of 2010 – data and tools which are already available online in some form but will be updated with respect to their content and formally registered on Data.gov

We present key highlights, below, with a particular focus on two divisions of HHS that are emerging as leaders of the next generation of transparency at HHS: the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA).

Centers for Medicare and Medicaid Services (CMS)

We are delighted to announce that CMS is embarking upon a transparency program of unprecedented scope and energy – a development of great importance to HHS and to the transformation of health care. Information is the lifeblood of health care improvement work. Without information, it is impossible to truly understand the current state of health care costs and quality and determine how to improve it. CMS is uniquely positioned to provide such information – and thereby providing transparency both into its own operations and also into American health care itself.

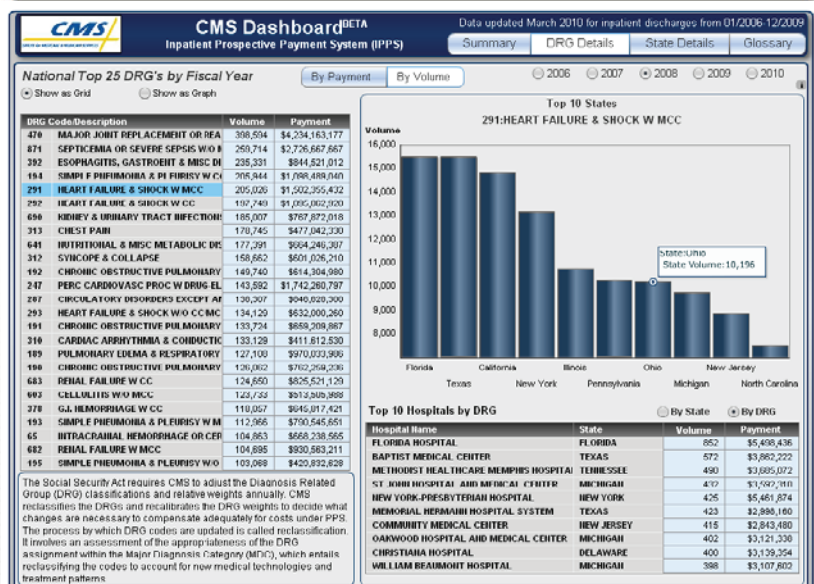
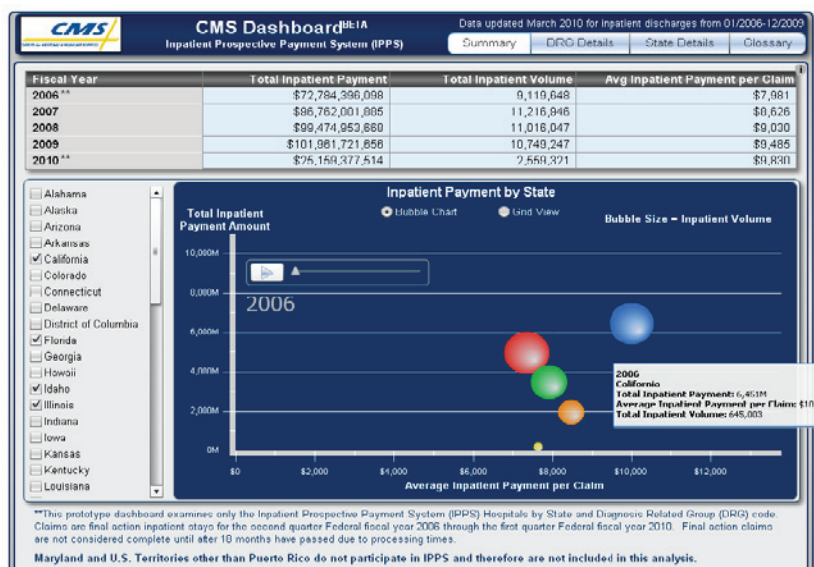
1. The CMS Dashboard. Launched in “beta” mode on CMS’s website on April 6, the CMS Dashboard (<http://www.cms.gov/Dashboard/>) is one of HHS’s official “Open Government Flagship Initiatives”

- The Dashboard is an exciting new web application which allows the public to visualize and analyze Medicare spending with unprecedented ease and clarity – beginning with inpatient hospital spending
- The initial version of the Dashboard allows users to track and graph Medicare spending on inpatient hospital services by state, by the top 25 “diagnosis-related groups” (DRG), and by top 10 hospitals for each state and diagnosis-related group over time. Users can also see how much Medicare is spending to support important public policy goals, such as the provision of medical education, additional funding to hospitals that take a disproportionate share of low-income patients, additional payments to rural hospitals, additional funding to hospitals who take cases that incur extraordinarily high costs of treatment, and adjustments for the underlying costs in different geographic regions.
- While much of this data had previously been available in some form to the public, scattered across hard copy and electronic publications, analysis of the data required retrieval of it from disparate places and having your own computer programmer and in-house Medicare expert to pull it together – barriers which the Dashboard now eliminates



- Furthermore, the Dashboard makes Medicare inpatient hospital spending data available to the public in a much more timely way than ever before. Data for a given quarter is published less than three months after the end of that quarter, vs. a previous publication lag time of up to 18 months
- Finally, the beta version of the Dashboard is just the beginning. After moving the Dashboard to full production mode, we plan to evolve and grow the Dashboard on an ongoing basis, adding more and more data and functionality – beginning with the next major release of the Dashboard in the fall of 2010
- The Dashboard will provide the public, researchers, policymakers, health care providers, and others with key information on the status of and emerging trends in Medicare service utilization and spending – insights which will help power better-targeted, more timely work to improve our health care system

Sample Screenshots from the CMS Dashboard





2. Creation of 9 Medicare claim “basic files,” including one for each major category of health care service, to be released from September to December 2010 for free public download on Data.gov. These files will contain a limited number of variables and be de-identified and configured through a rigorous process, in close consultation with privacy experts, re-identification experts, researchers, and key stakeholders, to ensure the protection of beneficiary privacy and confidentiality
 - As a by-product of administering Medicare, CMS maintains a comprehensive database of claims for all traditional Medicare beneficiaries (about 80% of the Medicare population) – claims from different settings and types of care, including (1) inpatient hospital, (2) outpatient hospital, (3) skilled nursing facilities, (4) home health, (5) hospice, (6) carrier (physicians and suppliers), (7) durable medical equipment, and (8) prescription drugs
 - To date, access to these claims has been very restricted
 - CMS is initiating a project to improve access to its data by creating “basic files” from claims data for public use
 - The primary product will be a set of “basic files” containing 2008 claims data for a randomly selected 5% sample of the Medicare population (about 2.4 million beneficiaries). There will be a separate file for each of the eight claim types noted above. CMS also plans to create an “enrollment file” describing the number and the demographics of the beneficiaries in the 5% sample to support the calculation of population-based rates and proportions
 - The files will be carefully stripped of information and include only a limited number of variables– hence the term “basic files.” This work will be executed through a rigorous and intensive process, consulting closely with privacy experts, re-identification experts, researchers, and key stakeholders, to ensure that beneficiary confidentiality is entirely protected. As a key note, each of these 9 files will be “stand-alone” files, published without identifiers that link claims across files to a given beneficiary -- to ensure that a beneficiary cannot be re-identified through their pattern of claims. The de-identification protocol applied to these files will also be such that claims will not be able to be linked to individual providers
 - We are planning to make these 9 files available to the public, downloadable at no charge, through Data.gov. The first of the claim “basic files” will be released in September 2010, and all 9 of them will be published by December 2010
 - This will represent the first time these kinds of data have been made available to the public
 - These files will allow users to study health care services provided through the Medicare program in ways never possible before. The effort is intended to enhance Medicare program transparency and can provide a vital spark for new research and innovation, ultimately leading to improved outcomes for Medicare beneficiaries and the Medicare program



- 3. Significantly improved user interface and analytical tool for the public to use to access CMS's existing COMPARE data on health care provider quality performance – launched with the rollout of this Open Government Plan at data.medicare.gov**
 - As mentioned previously, one of the most potent and useful data sets CMS has published on Data.gov is detailed quality performance data for individual hospitals, nursing homes, home health agencies, and dialysis providers across the country – a data set called “COMPARE”
 - This data can help consumers make better care decisions. Providers are using COMPARE data as an important tool to help them guide their quality improvement efforts, with measurable and discernible results. The COMPARE data set helps researchers gain new insights into care delivery, and aids policymakers in their decision making
 - While quite powerful, this data set has been difficult for users to utilize and manipulate in the past, hampering its impact
 - At data.medicare.gov, as of the rollout of this Open Government Plan, CMS has now launched a new user interface which the public can use to not only view the data much more easily, but also to customize that view by providing sort, search, and filter capabilities. In addition, users will be able to socialize and share the data through social media networking sites such as Facebook, Twitter, etc.
- 4. Medicare Part B National Summary File – now downloadable at no charge**
 - This file provides a detailed breakdown of the volume of physician services delivered to Medicare beneficiaries and how much Medicare paid for those services – by type of physician procedure. It can be used to look at trends in types of services delivered over time or to better understand the magnitude of the health needs of the Medicare population
 - This much-in-demand file was previously available for a fee of \$100 per year and only on CD ROM
 - On January 22, as part of the new high value data sets HHS delivered to the public as per the Open Government Directive, CMS made the 2008 Part B National Summary File available downloadable from Data.gov for free. Files from 2000-2007 are now also available for download from the CMS website for free
- 5. Medicaid State Plan Documents – to be put online on CMS's website by the end of 2010**
 - CMS has initiated a multi-stage project to place the detailed formal documents describing each state's Medicaid Plan (each of which is unique) on the CMS website, much as the documents describing the Children's Health Insurance Program State Plans are currently on the CMS website



- Through the Medicaid program, states and the federal government fund a wide range of health services for low income families, pregnant women, children, the elderly, and the disabled
 - The Medicaid State Plans are the legally binding documents that serve as contracts between the federal and state government. Each State Plan outlines in detail the nature of that state's particular Medicaid program, including benefits provided, populations covered and extensive details on the program's structure, financing and management. They are each accompanied by a stream of amendments that modify the program on an ongoing basis
 - Putting the State Plans and their associated amendments online will promote accountability and provide valuable information for citizens about what their government is doing
 - The process of compiling all plans and amendments, ensuring that they are complete and accurate, validating them with the states, and putting them online on the CMS website in a standard format should be completed by the end of 2010.
- 6. New community-level indicators of health care cost, quality, and utilization, to be supplied by CMS to the new HHS Community Health Data Initiative by the end of 2010**
- As a key part of HHS's new Community Health Data Initiative – another one of HHS's "Open Government Flagship Initiatives" – CMS will be contributing an exciting new set of metrics that describe community-level Medicare prevalence of disease, quality, costs, and utilization of services across the country at a national, state, regional, and potentially county level
 - These community indicator metrics, derived from Medicare data, will either be brand new to the world or at a finer level of precision than has previously been available to the public from other sources
 - Combined with other HHS data on the health and health care performance of communities, this vital new CMS data can be used by a wide variety of stakeholders to gain new insights into local health and health care performance and to develop new tools, strategies, and programs to improve the value of health care and health performance in local regions
 - For more on the Community Health Data Initiative, see the Flagship Initiatives section 5.5, page 58

Food and Drug Administration (FDA)

Like CMS, FDA is engaged in an unprecedented push to become more transparent. Two of FDA's initiatives are highlighted here as official HHS "Open Government Flagship Initiatives" -- the FDA Transparency Initiative and FDA-TRACK.



1. FDA Transparency Initiative

FDA Commissioner Dr. Margaret Hamburg launched the agency's Transparency Initiative in June 2009. Over the years, some stakeholders have complained about FDA's lack of transparency. The agency has been referred to by some as a "black box" that makes important decisions without explaining them. The objective of the FDA Transparency Initiative is to render FDA much more transparent and open to the American public. Increasing FDA's openness will help the agency more effectively implement its mission to promote and protect the public health by providing the public with useful, user-friendly information about agency activities and decision-making.

Commissioner Hamburg formed an internal task force representing key leaders of FDA to oversee the initiative. Commissioner Hamburg asked Dr. Joshua Sharfstein, the Principal Deputy Commissioner of the FDA, to chair FDA's internal task force, whose members include five of the Agency's Center Directors, the Chief Counsel, the Associate Commissioner for Regulatory Affairs, and the Chief Scientist. The Task Force was charged with soliciting public input on ways the agency can improve transparency and making recommendations to Commissioner Hamburg for ways the agency can operate more transparently to benefit the public health.

Over the last eight months, the Task Force has held two public meetings, launched an online blog (accessible at <http://fdatransparencyblog.fda.gov/>), opened a docket, and held listening sessions with representatives of regulated industry.

At the first public meeting, the Task Force solicited comments on how the Agency could improve transparency overall. Thirty five individuals provided comments during the meeting and 335 people attended in person or watched the live webcast of the eight hour session.

At the second public meeting, the Task Force solicited comments on three specific issues related to transparency at the agency: (1) early communication about emerging safety issues concerning FDA-regulated products, (2) disclosure of information about product applications that are abandoned (no work is being done or will be undertaken to have the application approved) or withdrawn by the applicant before approval, and (3) communication of agency decisions about pending product applications. Sixteen individuals participated in the groups convened to discuss each issue as well as during the open public session. One hundred seventy four people attended the meeting in person or watched the live webcast.

The online blog and the docket have received over 1,380 comments. The blog has offered an opportunity for exchange about specific ideas for transparency at the agency.

The Task Force is also collecting information on how to improve FDA's transparency to regulated industry. It held three listening sessions with members of regulated industry in January 2010 and have made available the transcripts and summaries of those listening sessions (accessible at <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/default.htm>).



The Task Force is proceeding with the Transparency Initiative in three phases:

Phase 1: FDA Basics. The first phase is intended to provide the public with basic information about FDA and how the agency does its work. In early January 2010, FDA launched a web-based resource called *FDA Basics* (accessible at <http://www.fda.gov/fdabasics>). The launch involved a media call and webinar with bloggers on FDA issues. This resource now includes (1) 115 questions and answers about FDA and the products that the agency regulates, (2) eight short videos that explain various agency activities, and (3) conversations with nine agency officials about the work of their offices.

The initial content for *FDA Basics* was based on questions and comments the agency frequently receives from the public. FDA will continue to add user-friendly information to the site.

In addition, visitors to *FDA Basics* can rate the helpfulness of the information provided and suggest additional questions for inclusion in *FDA Basics*. The agency has received over 2,700 comments from the public since the launch of the *FDA Basics* resource. Feedback provided by the public is used to update the resource.

Each month, senior officials from FDA product centers and offices host 30 minute online sessions about a specific topic and answer questions from the public about that topic. Each of these sessions is announced on the FDA web site, the online blog, and promoted to other stakeholders FDA employees identify.

The *FDA Basics* webinar series was launched in February with a webinar on “Access to Investigational Drugs,” hosted by FDA’s Office of Special Health Issues. An audio replay and copy of the PowerPoint slides from the session are available on the *FDA Basics* web site.

Early reaction to *FDA Basics* has been positive. One blogger wrote, “[t]he initiative can go a long way toward educating the public about what FDA does—and how—and also provide industry with real-time answers to their daily challenges, ultimately improving product quality and patient safety.” Another blogger wrote, “[i]t is really well put together, clear and works quite well. . . . The site is not only supportive of transparency, but is highly instructive and educational.”

Phase 2: Public disclosure. The second phase of the FDA Transparency Initiative relates to FDA’s proactive disclosure of information the agency has in its possession, and how to make information about agency activities and decision-making more transparent, useful, and understandable to the public, while appropriately protecting confidential information.

Phase 3: Transparency to regulated industry. The third phase will address ways that FDA can become more transparent to regulated industry, in order to foster a more effective and efficient regulatory process. FDA is now seeking public input through the Federal Register Notice process, and draft recommendations from this phase are expected in the spring of 2010.



2. FDA-TRACK

In addition to the FDA Transparency Initiative, the other FDA project to be designated an official HHS “Open Government Flagship Initiative” is FDA-TRACK, the FDA’s new agency-wide program performance management system. When fully implemented, FDA-TRACK will monitor over 90 FDA program offices through key performance measures that will be gathered on a monthly basis. Each quarter, the FDA-TRACK team will analyze monthly performance data, with senior managers presenting these data to FDA senior leadership.

Very importantly, the public will be able to track the agency’s progress through the FDA-TRACK website – which will debut in “beta” mode on April 7, with most of FDA’s offices represented.

Consistent with the principles of open government, FDA-TRACK adheres to values that comprise its name – **T**ransparency, **R**esults, **A**ccountability, **C**redibility and **K**nowledge-Sharing.

1. *Transparency* – The FDA-TRACK website (fda.gov/fdatrack) enables all interested external and internal visitors to view performance data at the program office level and gain a better understanding of the breadth of FDA’s core responsibilities, as well as see progress on important projects and programs. When fully implemented, the website will include data for over 300 performance measures and 80 key projects at the FDA. The website will be updated regularly so viewers can monitor the accomplishments and trends for each program area. Complementing the work of the Transparency Task Force, FDA-TRACK exemplifies FDA’s commitment to expanding public access to important information.
2. *Results* – FDA-TRACK highlights performance measures with relevance to the agency’s public health mission. These include the timeliness of reviews, the number of high risk inspections completed, and the completion of key research projects. Over time, FDA intends to include more measures that reflect public health outcomes across a broad range of agency activities.
3. *Accountability* – Developing, tracking and reporting performance measures will improve the agency’s accountability to the public. In addition, internal discussions between FDA’s senior leaders and program office senior management are conducted each quarter to promote sharing of ideas and hold each FDA office accountable for its priorities, plans and results.
4. *Credibility* – Sharing information about FDA performance is important for the agency’s credibility. The FDA-TRACK website will provide an unprecedented look into how FDA does its work. The site also allows visitors to submit comments on both the general features of the program as well as specific performance measures. Website hits and feedback will be monitored on a daily basis by the FDA-TRACK team, and suggestions will be considered as part of our continuous improvement efforts. A recent suggestion from early FDA-TRACK work led to the development of FDA-TRACK Dictionaries that provide a plain language explanation for each of the performance measures reported.




5. *Knowledge-Sharing* – FDA recognizes that we can improve our operational effectiveness through better collaboration and sharing of ideas. The implementation of FDA-TRACK will enable us to identify common issues and interdependencies among our program offices. As a result, program offices are working with one another as well as reaching out to other agencies to collaborate in achieving their performance objectives.

FDA-TRACK is a federal level adaptation of successful performance management programs from the state and local level. FDA's Office of Planning organizes and coordinates the FDA-TRACK process with all of the over 90 program offices across the nine FDA Centers and major offices.

Each of the program offices is responsible for collecting and providing monthly data in preparation for reporting performance via the FDA-TRACK dashboard (see Chart 1). The dashboards are presented to senior leadership through quarterly briefings. The data are then posted to the FDA-TRACK website.

Chart 1: Illustrative - FDA-TRACK Dashboard

 CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH) PREMARKET BUNDLE							
CDRH Premarket Program Measures				Quarter 1			
	Target	Jul 2009	Aug 2009	Sept 2009	Oct 2009	Nov 2009	Dec 2009
I Premarket Notification (510(k)) Review Measures							
Consolidated Offices (Office of Device Evaluation and Office of In Vitro Diagnostic Device Evaluation)							
A. Increase public access to medical devices by meeting MDUFA 510(k) premarket review decision goals.							
1. Percent of CDRH 510(k) decisions meeting MDUFA goals during the month	90%	93%	91%	90%	91%	92%	90%
a. Number of CDRH 510(k) decisions made in 90 days or less during the month (meeting goal)		270	210	241	249	217	257
b. Total number of CDRH 510(k) decisions made during the month		289	230	267	273	235	286
CDRH Office of Device Evaluation (ODE)							
A. Increase public access to medical devices by meeting MDUFA 510(k) premarket review decision goals.							
1. Percent of ODE 510(k) decisions meeting MDUFA goals during the month	90%	95%	93%	91%	92%	92%	90%
a. Number of ODE 510(k) decisions made in 90 days or less during the month (meeting goal)		246	185	215	223	190	227
b. Total number of ODE 510(k) decisions made during the month		260	198	236	243	206	253

FDA-TRACK publicly reports performance indicators and related data in four categories:

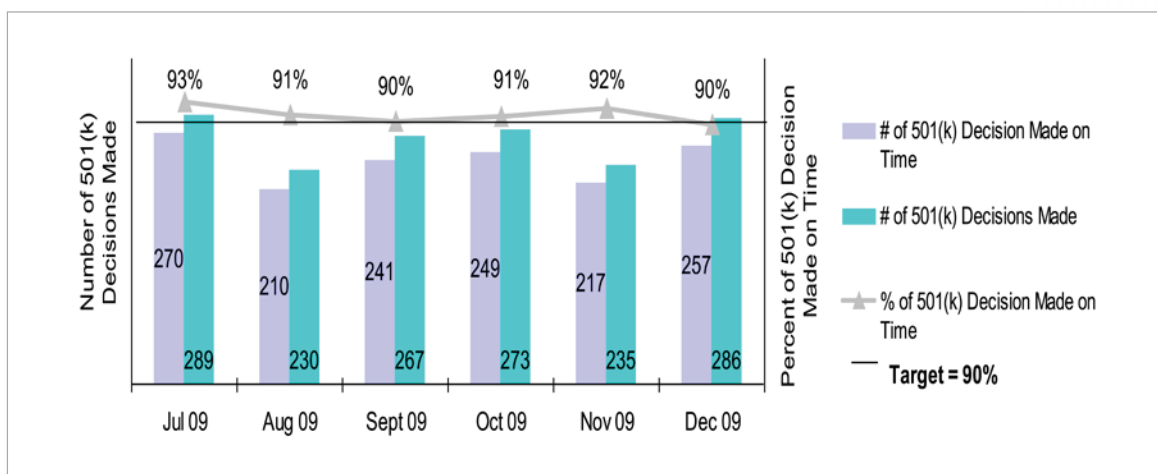
1. *Common Measures* – FDA-wide measures that are applicable to each of the over 90 program offices and may focus on the agency's most recent priorities. Example: increase the total number of employees who are trained in the Incident Command System (ICS), which helps the agency respond to emergencies.
2. *Key Center Director Measures* – Center-specific measures that are applicable to each Center and are central to the Center's priorities and strategic goals. Example:



increase the FDA's technical guidance by increasing the number of FDA technical publications, which enables the Center to better communicate with industry and consumers.

3. *Program Measures* – Program office-specific measures that are applicable to the office and reflect work important to the public and FDA's mission. Example: increase the percentage of 510(k) (or Class II medical devices) decisions made on time during the month (see Chart 2).

Chart 2: Percentage of 510(k) Decisions made on Time



4. *Key Projects* – Program office-specific projects that are applicable to the office and important to the mission and objectives of the office. Performance for Key Projects is measured through achievement of the stated milestones within the project's plan. Example: the development of a new risk-based approach for evaluating safety, effectiveness, and quality of new animal drugs.

The FDA's senior leaders are committed to making FDA-TRACK successful and sustainable. To accomplish this goal, FDA anticipates continuing to improve this program so it becomes an everyday essential management tool for all program offices. Planned improvements as FDA-TRACK matures include:

- Alignment of FDA-TRACK measures to the annual agency performance measures such as those required by the Government Performance and Results Act of 1993
- Alignment of FDA-TRACK measures to individual employee performance plans
- Improvements to FDA-TRACK data management and reporting software
- Improvements to measures based on public input and experience so that measures can be more closely tied to the public health mission of the agency
- Implementation of improvements to FDA-TRACK performance data analysis to enable better predictive outcomes and other quantitative data-based decision making

FDA is working to make FDA-TRACK a model for open government at the federal level.



3. Other FDA Transparency Actions

In addition to these initiatives, FDA is planning to post new summary aggregate data resulting from the new **Reportable Food Registry**, beginning in Q4 FY 2010. The FDA Reportable Food Registry contains information about foods for which there is a reasonable probability that the article of food will cause serious adverse health consequences or death. Regulated industry submits reportable food reports to FDA for possible inclusion in the Registry via an electronic portal. Federal, state, and local government officials may also voluntarily use the electronic portal to report information that may come to them about reportable foods. FDA plans to post reports summarizing certain aggregate data from the Registry online. In Q4 FY 2010, FDA also plans to enable the **FDA Recalls** website to provide drug, device, and food recall data in XML format to empower users to download, reuse or mash-up recall information.

Other Transparency Actions at HHS

In addition to the ambitious agendas being pursued by CMS and FDA, other divisions at HHS are pursuing notable new actions with respect to transparency as well:

- The **Administration on Aging (AoA)** will be posting a raw data set from the Annual National Survey of Older Americans Act Participants in Q4 FY 2010. This data has never been posted online in a downloadable format or otherwise been made available to the public as a data set.
- The **Centers for Disease Control and Prevention (CDC)** will be posting a brand new data set -- BioSense Condition-Specific Data, based on reports to the CDC's BioSense system from participating electronic health records systems (for example, statistics on dental-related emergencies that show up at hospitals).
- The **Office of the National Coordinator for Health Information Technology (ONC)** is in the process of developing a comprehensive performance measurement system and corresponding performance dashboard (**ONC Dashboard**) for its activities and programs. This Dashboard will assist ONC in monitoring its many programs and grantees, facilitate assessment of progress toward its goals, and position ONC to serve as a leading example of Open Government. In creating the ONC Dashboard, ONC will use information generated by its programs, its internal processes, its formal evaluations and other data collection efforts as needed. Given the wide range of measures to be collected, the Dashboard will have broad capabilities to support different stakeholders' need for information. ONC's performance planning is projected to be complete by late spring, with the beta version of the ONC Dashboard launched for public view before the end of 2010.

3.3 - New HHS Process for Ongoing Data Prioritization, Release and Monitoring

Equal in importance to the exciting new data sets and tools we are releasing is the new process which we will be implementing at HHS in 2010 for the identification, prioritization,



publication, and monitoring of data releases. This process will adhere to the following key principles:

1. HHS will continually review current inventories and portfolios of data sets and tools and identify high value data sets and tools for electronic dissemination in support of Transparency and Open Government goals.
2. At the planning stage for any new data development endeavor or major revision of existing data development efforts, and throughout the life of the project, HHS will identify opportunities for transparency, data sharing and dissemination through electronic posting of datasets. These dissemination activities will become part the project or system plan for the data project.
3. HHS will consider specific audiences, market segments and communication objectives in its data development and dissemination programs.
4. HHS will undertake efforts to foster the use and utility of the data it disseminates publicly through the web and seek feedback from data users.
5. HHS will ensure the quality, objectivity, integrity and utility of the substantive data it disseminates through compliance with HHS and Agency Information Quality Guidelines. <http://aspe.hhs.gov/infoquality>
6. HHS will employ feedback, outreach and evaluation mechanisms regarding the value and utility of the information we disseminate and use that information to enhance and improve our data products and services in a continuous quality improvement cycle.

Our updated data sharing process will be enmeshed into the department's core strategic planning, budgeting, and information technology planning activity in 2010. Key points:

- HHS will embed data experts on the strategic planning and management teams for each of the Secretary's strategic initiatives and cross-departmental priorities. The role of the data experts will be to 1) provide each strategic planning team with knowledge of current HHS data and information relating to the specific initiative, 2) assess data needs, gaps and opportunities, 3) develop plans and recommendations regarding the evaluation and performance information that will be used to implement and assess progress on the initiative, and 4) proactively identify and actively promote ways of sharing existing and new data with the public and key audiences in ways that adhere to transparency principles and advance the initiative. HHS's Data Council will identify one or more experts for each initiative who will bring not only subject matter knowledge to the team but will also serve as a resource regarding available HHS data systems which may support the initiative as well as principles of performance measures, evaluation and information quality. The data experts themselves will convene on a regular basis as a cross-HHS team to coordinate their work and share best practices across the department. Plans and recommendations emerging from each initiative will be employed by the HHS Data Council in its overall data planning and investment priorities.
- Data production and sharing opportunities proactively targeted by each Secretarial initiative will be added to an ongoing stream of new data sets identified for publication



on Data.gov through regular portfolio reviews conducted by each HHS agency and office and coordinated by the Data Council and CIO Council. The Data Council will ensure that data releases are screened for quality, privacy, security, and confidentiality risks before release. Data releases will be prioritized based on alignment with HHS's strategic goals.

- At the planning stage for any new data development endeavor or major revision of existing data development efforts, and throughout the life of the project, HHS will proactively identify opportunities for transparency, data sharing and dissemination through electronic posting of datasets on Data.gov. These dissemination activities will become part of the project or system plan for the data project. This new aspect of data and systems planning will be incorporated into the core management processes, templates and criteria utilized by HHS's information technology, investment review, and budgeting processes.
- Freedom of Information Act (FOIA) requests are one of the most reliable ways to know what information the public wants. HHS will establish governance within its FOIA operations to promote the proactive publishing of information and include FOIA officers across the department in transparency and data sharing planning activities. This approach will not only improve public access to information but could also help reduce the FOIA request backlog.
- Records Management – the Open Government Directive requires that if an agency keeps records in an electronic format (including those available online), it should develop a plan for the timely publication of the underlying data in an open, easily-discoverable format, and “as granular as possible.” HHS programs will analyze which records can be appropriately published and will develop a method to satisfy this Open Government requirement as we move forward with advancing the records management program. This activity will also assist in reducing the FOIA backlog, since some of the requests for information that HHS receives from the public are related to information that is contained in departmental records. HHS is engaged in an analysis of the current process for managing records and extending that process to the future of records management as a largely electronic process. This analysis will include an evaluation of which HHS electronic records may be the best candidates for publication to and review by the public.
- The Data Council will continue to oversee and manage the process of releasing information assembled via all of the sources above on our Open Government website and Data.gov.
- A key principle underlying our Open Government work is promoting transparency while maintaining confidentiality. This will require an ongoing effort involving those developing the data and data users and is made all the more challenging by the increasing amount of data from a wide variety of sources that conceivably could be linked to confidential data. The linkage could yield valuable insights but could also lead to the disclosure of confidential information. This challenge is shared by agencies across the government. HHS will work with other agencies to develop confidentiality safeguards for data submitted to Data.gov that will increase the amount and scope of data disseminated



while developing ways of preserving the confidentiality of the data's sources, whether individuals or businesses.

- HHS will engage in a proactive new program of monitoring, stimulating, and incorporating innovative and beneficial uses of our data.
 - On our Open Government website and through systematic dialogue with key stakeholder groups (overseen by our Data Council), we will solicit examples of how our data has been used to generate benefit. This will help us shape our future data release strategy on an ongoing basis.
 - We will establish an online forum on our Open Government website that facilitates public discussion of barriers to innovation using our data (e.g., data format, lack of metadata, etc.).
 - Leveraging the new “challenges and prizes” platform to be made available across the government, we will initiate an “HHS Apps Challenge” – a public competition for the most innovative and beneficial applications built utilizing our data.
 - Through our “Community Health Data Initiative” (one of our “Open Government Flagship Initiatives,” described in that section of the plan), we will test an approach in which we proactively and intensively market one major section of our data – data on community health care, health, and health determinant indicators – to potential utilizers who can turn it into applications and programs that benefit the public.
 - We will publicize innovative and beneficial uses of our data (insights, visualizations, applications, tools), with weblinks to these, as appropriate, on our Open Government website.
 - In the future, it is anticipated that publication of data could be enhanced beyond the current Data.gov to a more ubiquitous publication of data and information on the Semantic Web, which would provide even greater access to the public using already existing social media tools and the Internet as the access mechanism. This is an avenue we will explore.
- By employing these processes for ongoing data prioritization, release, and monitoring, HHS intends to increase the value produced by its information resources in several ways. Consumers will be able to access information and benefit directly from using it personally, as when somebody planning to travel familiarizes themselves with disease risks and vaccinations. Beyond that type of use, HHS intends for the information to prove valuable for improving public administration, positively impacting how we and other levels of government can deliver services and accomplish our missions more effectively, more efficiently, more rapidly, and with higher levels of customer satisfaction. A third source of value is the ability for our information to bring new transparency to the health and health care sectors, helping generate insights and spark action to improve performance. A fourth source of benefit is the value of our information to research -- the ability of those discovering and applying scientific knowledge to locate, combine, and share potentially relevant information across disciplines to accelerate progress. Finally, we intend for our massive public information resources to have entrepreneurial value,



to serve as a well-maintained community asset available to catalyze the development of new products and services that benefit the public and, in the process of doing so, generate private market economic growth fueled by innovation.

3.4 - Compliance with IT Dashboard, Data.gov, eRulemaking, Recovery.gov, and USASpending.gov Guidance

HHS is committed to improving access to data posted on central government websites to ensure greater transparency in programs and greater accountability for resources. HHS provides information to the IT Dashboard, eRulemaking, Data.gov, USASpending.gov, and Recovery.gov websites to increase public access to what we do, how we impact needy populations and communities, and how well we are performing in these areas.

The spirit of Open Government affords HHS an exciting opportunity to examine ways to streamline data and systems across functional areas to improve the completeness and the accuracy of our data. This section will describe the department's general approach to fostering high quality data and outline its current compliance activities. Additional steps to enhance the quality of financial data and address quality gaps will be outlined in HHS's Open Government Data Quality Plan, to be released subsequently in April 2010. By inviting the public to review our current data processes and transparency efforts, we hope to more fully engage the public in our ongoing efforts to improve data quality and resolve deficiencies in a timely manner.

Federal IT Dashboard

The IT Dashboard is a new website, launched by the Office of Management and Budget in June 2009, which enables federal agencies and the general public to view details of federal information technology investments.

What does the IT Dashboard Do?

The IT Dashboard helps the public review and track the spending, performance, and progress of technology investments over time. Users can obtain more information about the kinds of technology in which HHS is investing, who is performing this work, and other details of technology spending.

How is HHS complying with OMB IT Dashboard Guidance?

HHS has embraced the Federal IT Dashboard transparency imperative and fulfilled all associated requirements by integrating the Federal IT Dashboard with existing HHS IT investment governance processes, assigning HHS Chief Information Officer (CIO) IT investment ratings, focusing on timely updates and data quality, and establishing a new process to address public questions/concerns. The Office of the Chief Information Officer (OCIO) is responsible for administering these activities. HHS actions include the following:

- *Integrating Federal IT Dashboard with IT Investment Oversight:* HHS has integrated the Federal IT Dashboard into its existing IT review and oversight activities. This includes sending monthly updates of IT investment data to the Federal IT Dashboard and



incorporating reviews of information posted on the Federal IT Dashboard as part of monthly HHS IT investment reviews.

- *Assigning HHS CIO IT Investment Ratings:* In July 2009, in accordance with Federal CIO Rating guidance, HHS OCIO assigned initial CIO IT investment evaluation ratings to all of its major IT investments posted on the Federal IT Dashboard. HHS initial CIO evaluations focused on leading indicators of project success, including performance/risk management, quality of planning, and stakeholder approval.
- *Focusing on Timely Updates and Data Quality:* Since the Federal IT Dashboard was released, HHS has consistently updated its IT investment information on the Federal IT Dashboard by the last day of the reporting month to ensure the presentation of quality data to the public and for informing IT investment reviews.
- *Establishing a New Process to Address Public Questions/Concerns:* To engage with the public on IT investments, HHS has established a process for responding to a public inquiry on the IT Dashboard. The HHS OCIO is responsible for coordinating a response to public inquiry with the end communication issued by a Public Affairs representative.

Data.gov

Data.gov is a website sponsored by the Office of Management and Budget and federal agencies to increase public access to high value, “machine readable” federal data sets.

What does Data.gov provide?

Data.gov provides searchable data catalogs that present data in three ways: through a “raw” data catalog, a tool catalog, and a geodata catalog. HHS posts data under the “raw” data catalog and the tool catalog since much of our data are currently available in these formats.

How is HHS complying with the Office of Management and Budget’s Data.gov Guidance?

Since the launch of Data.gov in May 2009, HHS has mobilized its Operating Divisions and programs to identify and submit high-value data sets that allow the public greater access to downloadable data. Please review Section 3.1 for a description of the HHS data currently available for download on Data.gov.

HHS is committed to not only increasing the public’s ability to locate, access, understand, and use the data posted to Data.gov, but is also committed to monitoring and improving the quality of the high-value data sets we release. Details on planned actions to improve the quality of spending information on Data.gov will be outlined in the Department’s Open Government Data Quality Plan to be released in April 2010.

eRulemaking

eRulemaking is a current government-wide initiative committed to the following objectives:

- Increasing public access to and participation in developing regulations and other related documents that can impact the public
- Promoting more efficient and effective rulemaking through public involvement



How does eRulemaking work?

In 2003, the eRulemaking program launched the [Regulations.gov](http://www.regulations.gov) (<http://www.regulations.gov>) website to enable citizens to search, view and comment on regulations issued by the Federal government.

On average, federal agencies and departments issue nearly 8,000 regulations per year. In the past, if members of the public were interested in commenting on a regulation, they would have to know the sponsoring agency, when it would be published, review it in a reading room, then struggle through a comment process specific to each agency. Today using Regulations.gov, the public can shape rules and regulations that impact their lives conveniently, from anywhere. By accessing [Regulations.gov](http://www.regulations.gov) (<http://www.regulations.gov>), the public can view and comment on regulations with less burden and more engagement with agencies throughout the eRulemaking process.

How is HHS participating in eRulemaking?

A number of HHS Operating Divisions are complying with eRulemaking goals by using designated eRulemaking systems for their rulemaking activities. The Department's Food and Drug Administration (FDA) and Centers for Medicaid and Medicare Services (CMS) use the Federal Docket Management System (FDMS) -- a pillar of the eRulemaking initiative -- for their rulemaking business.

- **Process and Background:**

- CMS and FDA use FDMS to process all regulations and notices. Specifically, all regulations and notices published in the Federal Register are posted to Regulations.gov. With limited exceptions, public comments are processed and posted at Regulations.gov for public viewing.
- CMS issues an average of 150 Federal Register documents per year. FDA issued 705 Federal Register documents in 2009. The number of comments for each regulation varies, but in 2009 CMS received over 25,000 comments.

- **Benefits to the Public:**

- Fewer citizens have to go to FDA in person to view a document. The change has been dramatic. FDA public-room visits from visitors have decreased, from 1,203 in 2007 to 351 in 2009. And as a result of increased web accessibility, related FOIA requests decreased from 1,135 in 2007 to 323 in 2009.
- CMS staff note that FDMS has provided the public with greater access to CMS's regulations by allowing the public to view the CMS regulations online. In addition, FDMS provides the convenience of allowing the public to submit comments electronically and participate more easily in the rulemaking process.



- **Benefits to HHS:**

- FDMS has allowed better use of staff resources, because the public has virtually stopped submitting paper comments, instead using the FDMS to submit electronic comments
- CMS staff now manages public comments more efficiently. FDMS allows components within CMS to access the comments quickly, which in turn facilitates the development and clearance of policies more quickly

USASpending.gov

[USASpending.gov](http://www.usaspending.gov) is the Office of Management and Budget's response to the requirements of the Federal Funding Accountability and Transparency Act of 2006 (Transparency Act or FFATA). The Transparency Act requires a single searchable website, accessible by the public for free that includes for each federal award:

- Name of the entity receiving the award;
- Amount of the award;
- Information on the award including transaction type, funding agency, etc;
- Location of the entity receiving the award; and
- Unique identifier of the entity receiving the award.

How does USASpending.gov work?

Data on USASpending.gov are largely obtained from the following sources: the [Federal Procurement Data System](#) (FPDS), which contains information about federal contracts; and the [Federal Assistance Award Data System](#) (FAADS), which contains information about federal financial assistance such as grants, loans, insurance, and direct subsidies. Data are also obtained from agency submissions via OMB's FAADS PLUS file format.

How is HHS Complying with USASpending.gov Guidance?

Since 2006 HHS has achieved outstanding performance on USASpending.gov data transmission and compliance. Current performance is based on based on the timeliness and content of data submission. To view current HHS USASpending.gov performance, visit: <http://www.usaspending.gov/data/Agency%20Submission%20Summary02-09-2010.pdf>.

What about HHS' Financial Assistance Data in USASpending.gov?

To send assistance data to USASpending.gov, HHS uses its [Tracking Accountability in Government Grants System](#) (TAGGS). Grant data from HHS' Operating Divisions and Staff Divisions are submitted on a weekly and bi-weekly basis to TAGGS, and these data are reported to USASpending.gov on a bi-weekly basis. HHS has instituted data validation processes to ensure the consistency and accuracy of its grants award data.



What about HHS' Contract Award Data in USASpending.gov?

HHS uses its [Departmental Contracts Information System](#) (DCIS) to collect, report, and transmit contract award data to the Federal Procurement Database System (FPDS). DCIS receives data from HHS' contract writing systems. HHS relies upon the data validation and edit-check features found within FPDS to ensure the accuracy and completeness of its contract award data. The timeliness of each contracting offices' completion of the contract action reports is measured on a quarterly basis. These financial data are transmitted to USASpending.gov by FPDS on a bi-weekly basis. OMB posts these data on USASpending.gov on a bi-weekly and monthly basis.

What are the Identified Areas for Improvement?

HHS is building upon its current successes and actively working to improve the quality of financial assistance and contract award data in USASpending.gov. Although HHS has achieved outstanding USASpending.gov performance to date, HHS is currently developing its Open Government Financial Data Quality Improvement Plan, which will identify areas for improvement and associated costs, and will formalize a strategy to enhance the quality of spending information and sustain this work overtime.

Recovery.gov

[Recovery.gov](#) is the Office of Management and Budget's website to track and report on American Recovery and Reinvestment Act (ARRA) spending and to report fraud, waste, and abuse.

How is HHS Complying with Recovery.gov Guidance?

HHS has achieved full compliance with [Recovery.gov](#) mandates. The Department's strategic response to the requirements of ARRA and [Recovery.gov](#) was an unprecedented effort to mobilize, modify, develop, and enhance staff and resources to oversee the effective execution of over \$141 billion in ARRA funding. Specific ARRA activities include the following:

- **Submission of ARRA Financial and Activity Reports:** HHS submits a weekly ARRA Financial and Activity Report from the Department's financial management system to the Office of Management and Budget to provide the public with a snapshot of HHS' Recovery Act obligations and outlays.
- **Submission of Bi-Weekly ARRA Transaction Level Data:** OMB uses the Recovery Act transaction data sent to USASpending.gov to populate and update the [Recovery.gov](#) Total Funding Map, displaying total ARRA funding to States.
- **Recipient Reporting Support:** HHS provides additional support to ARRA recipients through an innovative web-based tool that assists grantees in locating, tracking, and understanding data for the quarterly recipient reporting requirements. The Recovery Act Recipient Reporting Readiness Tool (RRT), which is available at <http://taggs.hhs.gov/ReadinessTool/> enhances data quality for HHS and recipients by ensuring that data are synchronized in recipient and agency systems for quarterly reporting.



As a result of using this tool, HHS achieved a 99.4% OMB recipient reporting success rate. HHS was able to validate that over 99% of ARRA grant recipients complied with FederalReporting.gov requirements. Other achievements include:

- Lowering burden on recipients for reporting;
- Providing recipients a source of information for critical grant award data fields needed for OMB reports; and
- Bridging key gaps between state and federal award data and systems.

As a result of specific Reporting Readiness Tool outcomes, OMB has designated HHS's Reporting Readiness Tool as the primary model all government agencies should follow to improve ARRA recipient data quality and reporting performance.

3.5 - How HHS Will Inform the Public About the Business of Our Agency

The Department of Health and Human Services is deeply committed to the principles of Open Government and sees all of our communications efforts as ways to encourage and promote the goals of Open Government. Even prior to the Open Government Directive, HHS was using all of our Public Affairs assets to engage the public and our employees.

From the web videos, webcast forums and weekly reports on healthreform.gov to the flu symptom tool and the flu vaccine finder on flu.gov, to the helpful safe food tips on foodsafety.gov to the fraud finder map on stopmedicarefraud.gov, our goal has been to centralize and focus our communications efforts across HHS into easy one-step consumer campaigns.

We learned many important lessons during the 2009 H1N1 flu outbreak that we will be applying to our Open Government efforts. As part of our communications efforts around this pandemic, we developed new tools and protocols for the web, for our studio and for our advertising and media efforts that are not only helping us in Open Government efforts, but are also helping to change the way we have done business in the past. We will be building upon those principles, policies and practices as part of HHS's commitment to Open Government.

Our senior leadership will play a critical role in our efforts to communicate to the public about the transparency, collaboration and participation improvements we are making here at HHS. Secretary Sebelius is a strong supporter of New Media and from her first day in office has recorded web videos, done Facebook chats and led our webcasts.

3.5.1 - Accessibility

Open Government starts with ensuring that every American has access to the life saving health and human services materials and programs that HHS provides. HHS believes that "open" means open to all; we will do our utmost to remove barriers to participation by persons with disabilities. HHS is acknowledged as a leader in providing access, and freely shares its 508 standards, training, testing facilities, knowledge and experience and will continue to work at making its website information accessible to all.



3.5.2 - Assets

Broadcast

HHS and our operating divisions have several full-service television studios with experienced staff that can create and produce public service announcements, public webcasts, full-scale TV shows, daily press tours and press conferences. We are also investing in mobile video technology that can be used for web videos, interviews and press events. Wherever possible, we use our strong web and broadcast assets to promote training, research and collaboration.

Web

The department's websites, totaling more than 100 million pages, contain vast amounts of information. For legacy reasons, web content is largely organized by originating office or program. It's like a library whose bookshelves are organized by publisher. Utilizing content syndication and other emerging technologies, as now practiced on www.flu.gov, HHS is working to overlay a topically organized web experience to satisfy consumers' need for one-stop access to primary information.

Our work in food safety, AIDS, and flu tell us that the public wants to see our information organized in a way that presents clear, easy access. Later this year we will create new tobacco prevention and vaccine sites that will be modeled on the one-stop principle for presenting information.

We use usability testing and site visitor feedback to design our web pages and communications materials so that people can find what they want, when they want it. We strive to present consumer information using plain language.

New Media Center

The department has established a New Media Center to promote and coordinate the growing use of New or Social Media across the department. Social Media fosters direct interaction between the public and the department; enlists the public in the viral dissemination of important information; makes departmental health information available on countless other websites and applications; facilitates the use of open-source data sets and engages new demographic audiences in the public discourse. Social Media has already been used to convey critical health safety information addressing concerns ranging from the H1N1 flu pandemic to food safety recalls.

3.5.3 - Our Plan

Over the past year, HHS has adopted a specific set of policies and continues to develop others to increase our Open Government communications efforts. We have also initiated a series of activities to further improve Open Government at HHS. They are detailed below. Some of these are quick fixes and others will require work across the department.



Increased Access to HHS Events & Information

Beginning in April, HHS will publish a schedule of key events occurring across the Department each week, including events featuring key Departmental officials.

Whenever possible, we are working to webcast and tweet HHS press conferences, media events and informational briefings. Secretarial and Deputy Secretarial public/press events are taped and transcripts are made available on the web. We are working to add audio and video transcripts to our library on the website.

To bring transparency to one of our primary forums for public participation, starting in April, the Open Government website will link to all of the Department's Federal Advisory Committees.

Webcasts & Videos

HHS frequently uses webcasts and on-line videos to highlight the department's priorities, and we will be working to expand this capacity throughout the coming year.

We are working to create a library of on-line videos/tutorials to help consumers find critical data and information. Videos will show viewers how to use the tools on www.hhs.gov/open and our other one-stop websites and find the resources they need across the department.

One idea we are pursuing is to work with our Operating Divisions to create a series of day-in-the-life Web vignettes about individuals across the department, in which they describe how their jobs help Americans get critical health and human services.

In late spring, we are planning to unveil a weekly "Ask the Secretary" video feature on www.hhs.gov/open where the Secretary will answer a few questions each week that exemplify the range and types of questions that we are receiving from the public via the mail, the phones and on our websites.

Starting in May, the Department plans to schedule monthly webcasts on departmental priorities (a 30 minute show during the lunch hour broadcast live on hhs.gov). The webcasts will be hosted by the Secretary, Deputy Secretary and departmental leadership to discuss the program priority and the leaders behind it. News announcements and a featured 10 minute question and answer period from your emails and phone calls will often be featured on the webcasts.

Training

We will hold twice yearly Open Government trainings department-wide for communications staff. Training will also be provided for FOIA officers and coordinators.

HHS Open Government Website

The HHS Open Government website (www.hhs.gov/open) is first and foremost is a place where people come to work. It is designed to foster and model transparency. Content will value actions over words. Evaluation of and reaction to public input will be a hallmark of this site. The website fulfills three fundamental purposes:



- To facilitate the public's ability to access, interface and interact with the department's policies, goals and business processes.
- To make the department's informational holdings accessible in open and logical formats that permits their fullest utilization.
- To present the department's consolidated Open Government Plan in a transparent, user-friendly venue that invites broad public engagement.

Beginning with the release of our Open Government Plan Outline, each plan iteration will be presented on the Open Government website for public comment and discussion. The public is also asked to recommend data sets, tools, participation opportunities and other information that could be made openly available.

In addition, HHS Chief Technology Officer Todd Park blogs weekly on key Open Government Plan elements, suggests areas for discussion, and responds to plan comments and recommendations. To further the dialogue, his blog also invites general comment and discussion.

The Department's senior leadership will also post updates each on the Open Government Blog related to who we are and what we do.

Information and Data Sharing

HHS is committed to presenting its massive collections of data in accessible formats that allow and encourage the fullest use of this data. These open-format data collections will be made available on the Open Government website via a searchable contextual database. The site will likewise provide contextual database access to the department's many tools that facilitate transparency. HHS is committed to building on all of these collections and to listening to you regarding not only what is there, but also the best way to present our vast holdings.

The Open Government website will present the department's Annual Freedom of Information Act (FOIA) report in multiple accessible formats. As we discuss in detail later in the plan, HHS is committed to improved implementation of FOIA as we proceed with our Open Government plans. By significantly increasing web-based access to information and documents of interest, the Department is committed to reducing the need for people to submit FOIA requests.

HHS is making increasing use of new or social media to interact and interface with the public. The Open Government website provides direct one-stop access to the Department's new media engagement opportunities, including those on Facebook, Twitter and YouTube.

Privacy Page – Spring 2010

The companion of Open Government is a government that protects and advocates privacy – especially the privacy of people's personal medical information. To facilitate this, we plan to create a "privacy home page" that helps the public easily access information about the array of privacy protection programs that exist, the new regulations that are being created and the key privacy personnel who work every day behalf of the American people.



Trusting that your privacy will be protected as part of the on-line experience across the department is critical. It is important that HHS be an IT model of how electronic medical records and other new innovations are protective of privacy information while achieving the benefits of making information easily accessible on-line.

3.6 - How HHS Is Meeting Current Records Management Requirements

The results of the Records Management program at HHS are published on a publicly available website: <http://www.hhs.gov/ocio/policy/recordsmanagement/index.html>. These results demonstrate how HHS is carrying out records management requirements in accordance with NARA regulations and OMB mandates.

3.7 - HHS and the Freedom of Information Act (FOIA)

3.7.1 - Overview

The Freedom of Information Act (FOIA) gives the public the right to request records held by the federal government. Many agencies hold large backlogs of requests. The Open Government Directive recognizes this, and calls for a 10% annual reduction in “significant” backlogs. The HHS annual backlog at the end of September 2009 was over 17,000 requests.

To address this backlog and as a commitment to the Open Government Directive, HHS has initiated a strategic sixteen-week HHS Open Government FOIA Project with a dedicated project manager and team. This project is to assess the health of HHS FOIA operations, identify and prioritize improvement opportunities, and define a roadmap to implement the improvements.

The project is currently in progress. The project scope encompasses review of FOIA operations within the Office of the Secretary; the Program Support Center (PSC); and eleven HHS Operating Divisions, including the Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), National Institutes of Health (NIH), and Centers for Disease Control and Prevention (CDC). In addition, it includes collaborating with the FOIA offices of other federal agencies, to learn from successes in addressing FOIA backlogs. Some of the preliminary findings from the assessment, and the plan thereof, are presented in the subsequent sub-sections. Once the project is complete, this section of the HHS Open Government Plan will be updated with further details.

Section 3.7.2 provides a high-level FOIA assessment. Section 3.7.3 provides an analysis and preliminary plan, also at a high level.

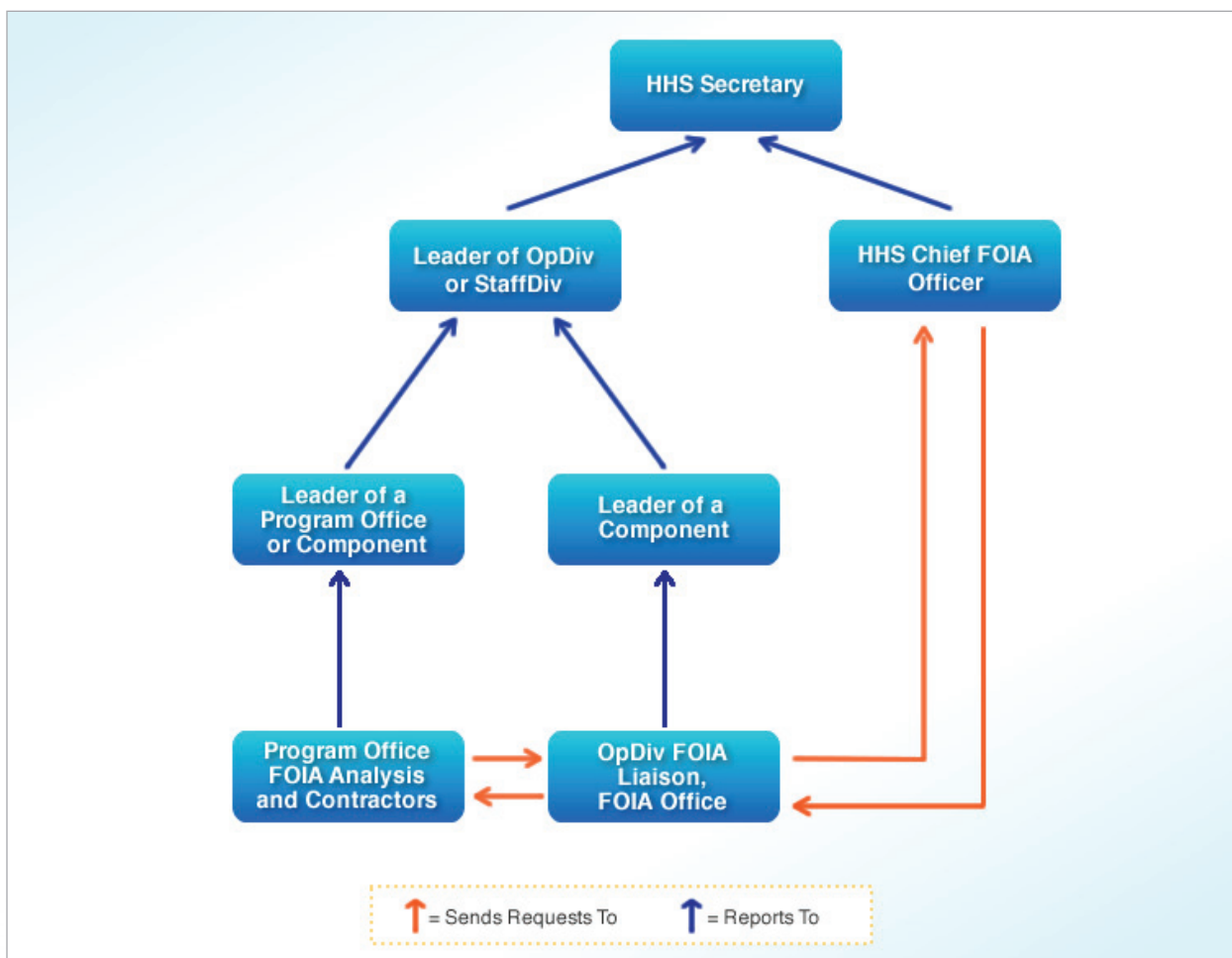
There is no single improvement that will solve the majority of the challenges facing HHS when it comes to FOIA. In the spirit of openness, many of the ideas in this plan are being shared while still under early investigation. However, it is clear that a multi-pronged approach will be necessary for backlog reduction: enhanced FOIA program efforts, the implementation of metrics for FOIA office performance, and an increased use of supporting technologies.



3.7.2 - Assessment: Current State

3.7.2.1 - Organization

- a. **FOIA Organization at HHS is Decentralized.** There are thirteen HHS FOIA offices, located in various Operating Divisions and Staff Divisions (components of the Office of the Secretary). Each FOIA Office is run by a local FOIA Officer. Operating Divisions such as FDA and NIH have numerous “satellite” FOIA offices located within their institutes and centers. The entire FOIA program, though decentralized, is the responsibility of the HHS Chief FOIA Officer, the Assistant Secretary for Public Affairs.



FOIA offices and related positions (e.g., the FOIA public liaisons) are managed by the leadership of their respective Operating Divisions and Staff Divisions, including budgeting and staffing decisions.

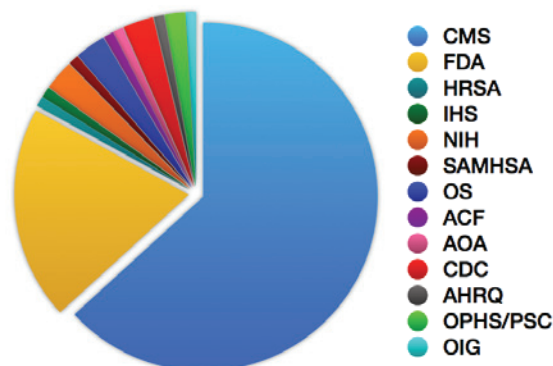
- b. **Funding Towards FOIA is not Transparent to the FOIA Offices.** Most FOIA offices do not have their own budgetary allocation. Instead, their funding comes from the offices to which they report. The reporting structure of FOIA offices within different Operating Divisions varies. For example, in the FDA, the FOIA office is part of the



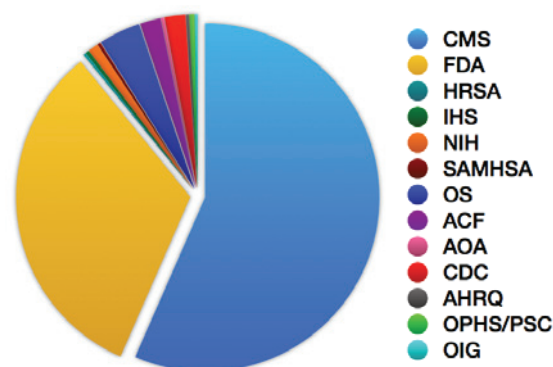
Office of Public Information and Library Services, whereas at CMS it is part of the Office of Strategic Operations and Regulatory Affairs.

- c. **88% of FOIA Requests are Concentrated in Two Agencies.** The number of FOIA requests received varies greatly across the Department. For Fiscal Year 2009 (FY09), the Department as a whole reported receiving 48,564 requests. Of these, 88% were received by two FOIA offices – 67% (32,541) went to the CMS FOIA office, and 21% (10,337) went to the FDA FOIA office. The remaining 12% of requests were received by the other eleven FOIA offices. Of these, the CDC and NIH FOIA offices received 3% (1272 and 1270, respectively) each. The Administration on Aging (AOA) received the least number of requests (only ten).
- d. **93% of Backlogs are Concentrated in Two Agencies.** Within HHS, 59% of backlogged requests (10,312 requests) are with CMS, and 34% (4,818) are at FDA. The next largest contributor is the Office of the Secretary (OS) FOIA Office, which holds only 4% of the backlogged requests. The Department is therefore focusing on these areas for backlog reduction.
- e. **FOIA Requests Vary in Complexity.** Not all requests are equivalent. Some requests require the careful review of thousands of pages, while other requests are easily granted with a single page record that needs no redaction. The definitions for “simple request” and “complex request” vary between FOIA offices, as do the definitions for “partially fulfilled” and “fully granted.”

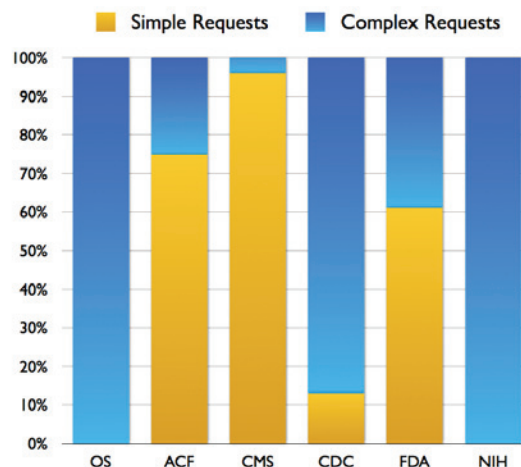
Percentage of FOIA Requests in FY09



Percentage of FOIA Requests Backlogged at End of FY09



Ratio of Simple Requests to Complex Requests





- f. **Backlog reduction efforts are decentralized.** Under the Open Government Act of 2007 and Executive Order 13392 (2005), agencies were directed to develop FOIA improvement plans with backlog reduction goals. At HHS, no comprehensive or department-level activities were implemented in this regard. However, overall department backlogs were lowered as some Operating Divisions have shown progress individually in the last few years.

3.7.2.2 - People

- a. **FOIA Analysis Requires Specialized Knowledge.** The responsibilities of FOIA staff vary greatly, and only some perform the disclosure analysis necessary before a record can be released. FOIA disclosure analysis requires knowledge of not only the Freedom of Information Act and the amendments, executive orders, and Operating Division policies that have augmented it, but also comprehension of the 36 years of case law that have come since the Act itself and related statutes as well. In addition, some HHS Operating Divisions, such as FDA, review documents that are rich in technical and scientific content – work which requires additional educational background, knowledge and training to process and accurately redact requests.
- b. **Operating Division FOIA Operations Vary in Scale.** There are 264 full-time equivalent (FTE) FOIA personnel at HHS. Of the thirteen HHS FOIA offices, all have less than seven of these FTEs except NIH (30 FTEs), CMS (67 FTEs), and FDA (124 FTEs, up recently from 108). Almost all of the FTEs at these three Operating Divisions are satellite personnel, with different roles depending on the Operating Division.

3.7.2.3 - Process

- a. **FOIA Requests Mostly Arrive by Mail.** Most HHS FOIA offices do not offer an online FOIA request form, so requests come largely by mail, fax, email, and (for commercial requestors) courier services. The Departmental FOIA office offers a web form that generates an email to the Office of the Secretary's FOIA office, which then manually forwards the email to the appropriate HHS FOIA office. While this adds convenience for the requester, no internal efficiencies are gained through the current system.
- b. **Request Tracking Capabilities are Minimal.** All Operating Divisions are required to provide tracking information to their requestors, but only CDC allows users to do this on the web; the rest handling status tracking more manually. Requests are processed internally at the smaller FOIA offices, but the larger operations at CMS and FDA have most of their requests fulfilled by satellite FOIA personnel.
- c. **Annual Reporting is Manual.** Although the annual report requires the collection of several numbers that might serve as good performance indicators, this is undermined by inconsistencies in the definitions for the terms in the report. A complex request in one FOIA office might require a significantly different amount of work than a complex request in another. The annual report shows nothing of whether long delays are due to fundamentally difficult redaction questions, due to slow response time of the program holding the records, or due to a backlog in disclosure analysis. Since the Department's annual report is compiled manually, more frequent collection of metrics is not feasible without systematic changes.



3.7.2.4 Technology

- a. **Technology is Underutilized.** The challenges encountered in compiling the annual report underlie the differences in technology utilization across the HHS FOIA offices. Most of the HHS FOIA offices do not offer online submission of requests. There are little or no common standards connecting any of the systems supporting HHS's FOIA offices.
- b. **Technology at CMS.** CMS currently uses Strategic Work Information Folder Transfer (SWIFT) to manage its correspondence and is in the process of adding more FOIA-specific functionality to this software. CMS's backlogged requests, however, are not yet part of this new system.
- c. **Technology at FDA.** FDA as a whole is using an in-house customization of Documentum to track Operating Division tasks and dockets, including the tracking of FOIA requests. FDA's FOIA office is beginning to use commercial software for redaction, and most component offices have used redaction software for years.
- d. **Technology at NIH.** NIH uses a custom-built tracking system, and uses physical redaction tape or commercial software for redaction depending on the NIH program office.
- e. **Technology in OS.** The Office of the Secretary's FOIA Office uses Microsoft Access to log requests, and prepares the annual report in Microsoft Word.

3.7.3 - Analysis and Preliminary High-Level Plan

The following proposals are high-level ideas, presented to receive public and employee input. Amendments will be made based on input or feedback received.

3.7.3.1 - Better Use of Available Information

- a. **Trends and Outliers in Requests.** FOIA requests are one of the most reliable and quantifiable metrics for the public's interest in government. However, throughout HHS, FOIA is very rarely part of the strategic planning process. FOIA should inform Open Government activities, the proactive publishing of datasets, and website content. Accordingly, HHS will look into integrating the FOIA offices into Operating Division and departmental processes, committees, and meetings (e.g., capital planning, the Data Council, the CIO Council, the Innovation Council, the Web Council, budget and contract planning, strategic planning, Open Government and transparency, etc.).
.....
Including FOIA staff in more strategy meetings will bring matters of public interest to the attention of HHS leadership.
- b. **Prioritizing Information for Proactive Release.** The FOIA workload can be reduced, and service to the public can be improved, by the proactive publishing of frequently requested datasets. HHS will establish
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Requests that are easily granted and frequently submitted indicate datasets that will be proactively published.



governance to include FOIA officers across the department in transparency and data sharing planning activities.

- c. **Submission and Tracking of FOIA Requests.** Requestors are already able to ask FOIA offices for the status of their request, but a robust tracking system would make this available online and could include the status of all requests. HHS will explore setting minimum standards for the online submission and tracking of FOIA requests across all Operating Divisions. Tracking requests is also crucial to ensuring appropriate resources are allocated for FOIA operations; this is discussed in 3.7.3.2.e, below.
- d. **Technology Architecture.** HHS is actively investigating whether the centralization or federation of technological resources used in processing FOIA would be a significant improvement over the current decentralized approach. Similarly, the HHS FOIA websites vary in features and content, and HHS is investigating whether more uniform standards or centralization of HHS FOIA web tools would bring added value to the public.
- e. **Instituting a Performance Management Culture.** Metrics showing the health of the FOIA program will be defined, and systems will be put in place to capture and report metrics to the Chief FOIA Officer on a least a monthly basis. FOIA metrics developed by HHS will be shared with other agencies.

3.7.3.2 - Ideas for Improving FOIA Processes

The following list is preliminary and presented in order to receive input on ways to strengthen FOIA at HHS, address the deficiencies that have led to the significant backlog of requests, and achieve excellence in FOIA administration. This list is not a final plan; the assessment of HHS FOIA operations and planning for remediating issues is still in progress.

- a. **Communicating FOIA Needs.** The decentralized FOIA operations at HHS allow FOIA offices to be close to the programs that have the information that is being requested. It is possible to improve communication between FOIA offices and Operating Division leaders through the same strategy described in 3.7.3.1.a; that is, better integration of FOIA into existing activities.
- b. **FOIA as a Senior Executive Priority.** While FOIA needs will be better addressed through increased participation of FOIA personnel in Operating Division governance, leadership attention to FOIA performance will also make a difference. HHS will explore methods for increasing senior management attention to improving FOIA operations within its operating divisions.

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To achieve excellence in FOIA processing, senior executive attention is needed.
- c. **FOIA as a Program Officer Priority.** Federal employees who are not FOIA staff play a crucial role in fulfilling FOIA requests. Such individuals hold the records sought through the FOIA process, and are a critical step in the process. However, communication to employees about FOIA responsibilities and statutes

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All non-FOIA staff should understand their role in the FOIA process and make it a priority.



is lacking. In addition, few receive training in FOIA. HHS plans to consider ways in which FOIA compliance and training as can be promoted and measured as part of an HHS-wide effort.

- d. **Matching Skills and Needs.** There is no FOIA-specific job series within the federal government, which means there is no government-wide standard for the skills and knowledge necessary to perform FOIA work, no standard for evaluating performance by FOIA staff, and considerable inconsistency in how duties map to salary grades. This need can be met, at least in part, through the efforts to create HHS standards, by better capturing metrics, and through better tracking of requests.
- e. **CMS FOIA Backlog Planning.** CMS has developed a short term strategy to take necessary steps to increase case production of existing staff, align contractor resources, and focus regional resources to decrease the existing backlogs. CMS has been charged with developing a long range plan to ensure new backlogs are not created; this plan will include an analysis of resources that may be needed moving forward as well as addressing the need for all aged, pending complex cases to be converted from paper to electronic files for better case management and electronic review and redaction.
- f. **FDA FOIA Backlog Planning.** At FDA, of 4,600 backlogged requests, the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) have approximately 2,000 each. Both offices are built around FOIA staff with not only the standard amount of FOIA knowledge, but also a familiarity with the underlying technologies/sciences specific to their program areas. FDA is committed to backlog reduction through a multi-pronged approach. The agency is currently evaluating the best alternatives to achieve this goal, and anticipates building on the significant (75%) backlog reduction that has occurred since FY2007. Much of the FDA reduction was accomplished by categorizing and resolving large sets of requests in the backlog, and with these requests now closed, the remaining backlog may require new approaches.
- g. **Office of the Secretary FOIA Office Backlog Planning and Program Development.** The Office of the Secretary is doing everything it can to reduce its backlog, and is considering additional FOIA-specific activities, including maintaining department FOIA regulations, creating a department-wide FOIA council, and providing cross-training for both FOIA and non-FOIA staff. Also being considered are mechanisms to cooperate with the new Office of Government Information Services' FOIA mediation efforts and regular meetings between FOIA professionals and the agency Chief FOIA Officer.

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The OS FOIA Office must provide timely responses to FOIA requests and provide department-wide FOIA Program support.

3.7.3.3 - Doing More With Less

- a. **Communication for Greater Efficiency.** The simplest method for reducing FOIA backlog and workload is to encourage FOIA staff to work with the requestors to make sure their requests are being interpreted as intended. This method is proven in some



components of HHS but is not routine across the department. To reduce the routine waste in fulfilling too broad, obsolete, or ambiguously worded requests, HHS may institute policy regarding communication between the analyst and requestors and establish guidelines to improve direct communication between reviewers and requestors.

.....
*Better communication
between requestors and
reviewers is a best practice.*

- b. Technology.** As explored in earlier sections, technology solutions can improve FOIA service to the public and management oversight, as well as bring new levels of transparency to the process itself. Technology investments should also result in faster responses and more efficient disclosure analysis; HHS will include these priorities in considering new technology to support FOIA operations.

3.7.4. - Conclusion

These are high-level preliminary plans, and will be updated based on public and employee feedback. Public input will help ensure that the agency meets its goal of excellence in FOIA administration.

More background on the department's FOIA program is available in the 2009 annual FOIA report and the Chief FOIA Officer's report, both of which are available on the HHS FOIA website.

3.8 - HHS and Congressional Requests for Information

The Office of the Assistant Secretary for Legislation (ASL) serves the Secretary as the primary link between the Department of Health and Human Services (HHS) and Congress. In addition, ASL liaisons with agency legislative staff to advocate for the department's priorities and goals.

ASL Divisions

The office consists of six divisions:

Immediate Office of the Assistant Secretary for Legislation: Serves as principal advisor to the Secretary with respect to all aspects of the Department's legislative agenda and Congressional liaison activities.

Office of the Deputy Assistant Secretary for Discretionary Health Programs: Works on the legislative agenda and serves as the lead liaison for discretionary health programs. This portfolio includes health-science-oriented operating divisions of the department including the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Office of the Assistant Secretary for Preparedness and Response, and the Surgeon General, among others.

Office of the Deputy Assistant Secretary for Mandatory Health Programs: Works on the legislative agenda and serves as the lead liaison for the Centers for Medicare and Medicaid Services as well as the Indian Health Service.



[Office of the Deputy Assistant Secretary for Human Services](#): Works on the legislative agenda and serves as the lead liaison for the departments' human services and aging program divisions.

[Congressional Liaison Office](#): Serves as the lead liaison to Members of Congress by notifying them of departmental activities and initiatives, maintaining the Department's grant notification system and coordinating agency response to congressional inquiries.

[Office of Oversight and Investigations](#): Responsible for all matters related to Congressional oversight and investigations, including those performed by the Government Accountability Office.

The organizational structure chart and staff list for the Office of the Assistant Secretary for Legislation can be found at: <http://www.hhs.gov/asl/divisions/divisions.html#clo>

Grants

The ASL Congressional Liaison Office (CLO) responds to congressional inquiries about grant awards; notifies congressional offices of grant awards made by the Department; and facilitates technical assistance regarding grants to Members of Congress and their staff.

ASL grant information can be found at: <http://www.hhs.gov/asl/Grants/grants.html>

Testimony

A complete listing of testimony by the Secretary and other Department officials before the United States Congress.

HHS testimony can be found at: <http://www.hhs.gov/asl/testify/2010/testimony.html>

3.9 - HHS and Information Declassification

In general, any documents held at HHS that have a national security classification bear that classification from another source. Decisions and the process for the declassification of this material rest with their originators.



4 - Participation and Collaboration

The term “Open Government” may at first conjure up the image of improved communication and transparency. Indeed, as outlined above, our Open Government work will look toward achieving new levels for those goals: more effectively communicating factual and helpful information to Americans; moving to make the Department’s unique data resources more easily available; and putting new emphasis on transparency and “sunshine” in our information and decision-making processes.

But to have maximum positive impact, the goal of Open Government must also look beyond these traditional areas. Building on a foundation of open information, we will also seek to take Open Government to the next level – expanding opportunities for public participation and collaboration in HHS activities, especially by engaging new information and communications technologies. Our Open Government work will break new ground in enabling the public to give feedback to HHS programs. We can help stakeholders contribute knowledge and experience that will help us do our jobs better, and we can support new kinds of collaborative teamwork that will deliver better results for our citizens. We will move forward toward new strategies, new tools and indeed a new culture of public participation and collaboration in HHS affairs.

In truth, HHS is a department built on the idea of collaboration. Hundreds of health and social service programs are brought together in this department with the goal of achieving synergistic progress across programmatic lines, especially toward the goal of serving Americans in need. Most of our divisions oversee programs that involve collaboration and partnership with the states and counties that actually administer our programs “on the street.” Much of our work is carried out through grant and contract programs in which we and our partners collaborate with local organizations. For example:

- In protecting the public health, the work of the Centers for Disease Control and Prevention and the Food and Drug Administration could not be carried out except as a complex network of state, local and professional resources.
- In conducting the world’s largest biomedical research enterprise, the great majority of research sponsored by the National Institutes of Health is for extramural research conducted throughout our country. These research programs are guided by policies developed with the advice of non-federal professionals and health advocacy organizations.
- In managing the nation’s largest health insurance programs, our Centers for Medicare & Medicaid Services are the de facto meeting and negotiating ground for every element of our nation’s health care system. And in delivering health coverage to millions of Americans, the success of these programs success depends on fostering two-way communications.
- In protecting our children, the programs of the Administration for Children and Families rely on collaboration with other federal departments, states, law enforcement agencies and volunteer organizations.



- The success of the Head Start program derives strongly from its collaborative nature. It was conceived as a collaboration, not only with the community organizations that run Head Start centers, but more importantly with Head Start parents themselves, who are integral to the program's management and operations at the ground level.
- To reduce the impact of substance abuse and mental illness on America's communities, the Substance Abuse and Mental Health Services Administration (SAMHSA) works closely with 60 states, tribes, and countless local communities in the development of their behavioral systems through strategic block grant investments, technical assistance, data collection, evaluation activities, and special safety net programs.
- In supporting health care providers and programs to improve access to quality and culturally competent health care services for people who are uninsured, isolated, and medically vulnerable, the work of the Health Resources and Services Administration (HRSA) is accomplished with continual engagement with the populations it serves.

Thus, as HHS looks toward new horizons of participation and collaboration, we have a strong foundation on which to build. But we are also at an inflection point, where new progress is both needed and feasible. On the one hand, program complexity has grown, and the links across programs that were envisioned in the creation of HHS need to be renewed and revived. At the same time, information and communications technologies offer new tools and opportunities to support new kinds of participation and collaboration.

New tools and new policies will enable us not only to rejuvenate the important areas of participation and collaboration that already exist, but also to achieve a new level of Open Government. We can better support our own employees in team-building and innovation. We can forge stronger and more supple ties with our traditional partners, both in and out of government. And we can provide new opportunities for every citizen to contribute toward better performance by our department as well as improved health and well-being for our fellow citizens.

4.1 - Participation – How HHS Currently Engages the Public

HHS has a large number of activities that provide a means for citizen participation in agency activities such as planning, priority setting, or community involvement. In developing a composite of our current approaches for public participation, we began by asking: "How does my agency include public participation in agency matters, and what will it take to revise its current practices to increase opportunities for the public to participate in and provide feedback on the agency's core mission activities?"

There are several mechanisms that are widely applied across HHS to engage public input. A key approach is the convening of meetings and public forums such as HHS federal advisory committees that are either agency specific, cross-agency, or interactive with multiple federal agencies. Federal advisory committees are created to advise the Department on a specific topic. By law, the membership must fairly represent diverse points of view. These committee activities draw upon subject matter experts to provide context for issues and facilitate engagement with the public to address barriers and opportunities on particular issues of importance. Committee meetings are convened by the government and, with limited



exceptions, held in the public domain. The committees develop reports and other products that help provide input to the government on a wide range of health and human services issues.

Formal input into HHS agencies' federal advisory committees represents an important opportunity to participate in policy and planning activities. Virtually all public meetings of these bodies include representation by public members and are open for individual formal comment submissions. Many of these bodies also provide opportunities to follow the proceedings via the web or by phone, enabling remote participation. HHS strongly encourages public participation in these meetings and provides here a resource to identify these committees of interest and resources about them. You can find out information about these committees and how to engage with them through this portal: <http://www.hhs.gov/open/getinvolved/index.html>

Another approach is the development of networks with non-governmental, academic, state and regional government and other organizations to take on specific challenges. Other approaches to encourage participation are to work with the media to highlight focused activities such as health promotion, prevention, and emergency preparedness. These include special events that mark certain periods of time during the year for featuring a particular cause with press events, town hall meetings, webinars, and broadcasted events that aim to allow the public to observe and submit questions and comments to government representatives. Yet another approach that HHS uses is to develop agreements with organizations, such as universities, colleges, professional societies, and other non-governmental organizations, to facilitate community engagement activities.

Increasingly, HHS organizations are turning to electronic communications as a means to connect with the public. While the Internet has been a main pathway of communication to the public for many years through websites and databases, it is now being used to interact with the public. Information dissemination to the public has advanced using the Internet and mobile communication technologies, such as the use of rapid syndication feeds for broadly disseminated publishing of accurate health information to other websites and automated text messaging. These have been an important part of providing trusted and verifiable source information to the public, and in turn, provide the public with information that enables citizens to respond on important issues. Electronic technology is also being used to gain input from the public through new Web 2.0 technologies. Among the techniques and methods that are becoming popular in federal agencies are web dialogues, blogs with federal organization leaders, microblogging (such as Twitter), video connectivity through YouTube, idea generation tools that include rating and rankings of ideas by the public, on-line collaboration tools, and hosted jams that engage a wide array of participants in an on-line group discussion. In some cases, the public and experts are using web technology to develop documents through group writing efforts that enable more efficient and wider participation with knowledge in the specific activity.

A prominent case example at HHS with respect to intensive use of Internet technologies and approaches is the Centers for Disease Control and Prevention (CDC). CDC has used podcasts and RSS to cover topics from H1N1 to emergency preparedness to chronic disease. CDC podcasts have been accessed over 8.4 million times, and CDC RSS feeds have been consumed 31.4 million times. CDC has launched Health-e-Cards as another means of providing interactive media activities to help disseminate public health information. Since



its launch, over 110,625 e-Cards have been sent and over 313,767 cards have been viewed from the site. CDC has also served as a pioneer in the use of virtual worlds to expand the reach of health messages. Whyville and Second Life have been used by CDC to promote vaccination campaigns, share information about CDC's mission and goals, and provide access to streaming video, posters, and links to CDC website information. CDC has extended federal public health use of Web 2.0 technologies into social networking sites and microblogging (with 1,251,936 followers on Twitter). CDC's development of widgets and web gadgets have led to over 55.4 million interactions, while buttons and badges have been a source of over 2.6 million click-throughs in 2009.

There are many other ways to participate and engage in HHS activities. We encourage participation by the public in a variety of ways – a sampling of these opportunities is provided in our “Get Involved” searchable resource. (<http://www.hhs.gov/open/getinvolved/index.html>) This resource allows the user to search by topic area or agency.

4.2 - Collaboration – How HHS Agencies Work with Outside Entities

There are several common approaches to collaboration across HHS. There are a large number of interagency or collaboration agreements with other federal agencies and with non-federal partners. Many of these are targeted to specific activities such as implementing quality improvement methods, patient safety methods, evidence-based health care practices, facilitation of healthy behaviors, etc.

In developing a profile of HHS collaborations, the following was addressed in a survey of the organization: “How does your agency foster collaboration, and what approaches will your agency take to revise its current practices to further cooperation with other Federal and non-Federal government agencies, the public, and non-profit and private entities in fulfilling the agency's core mission activities?”

Notable examples of collaboration are articulated by the National Institutes of Health's (NIH) annual report on collaboration efforts with other agencies. As required by the Public Health Service (PHS) Act, NIH must provide the Secretary with a report including detailed information on all of its activities and collaborations with other HHS agencies. These include hundreds of collaborations in areas of health such as autism, HIV/AIDS, childhood vaccines, and dozens of other diseases, as well as collaborations on the creation of resources and infrastructure in the realms of IT architecture, unique databases and data collection and evaluation. NIH engages in major international collaborations to study and ameliorate or eliminate disease and has a formal program of public-private partnerships addressing major scientific discovery. For example, the Biomarkers Consortium, a unique public-private partnership that includes FDA, NIH and major pharmaceutical companies, led by the Foundation for NIH, just announced the launch of a clinical trial, I-SPY2, to help screen promising new drugs being developed for women who have high risk, fast-growing breast cancers – women for whom an improvement over standard treatment could dramatically change the odds of survival.

At the FDA, there are many examples of collaboration with other agencies within HHS, other federal agencies, and with state, local and foreign governments. The FDA works closely



with state and local public health departments to protect the nation's food supply. Recent activities include the opening of a center, operating under the direction of Customs and Border Protection, to work with FDA and other agencies on matters relating to the safety of foods imported to the United States, to which FDA is providing on-site expertise. FDA collaborates with CDC, USDA, and state and local public health departments on surveillance, investigation, and response to outbreaks of food-borne and other enteric illnesses. Additionally, through the Food Emergency Response Network (FERN), FDA integrates federal, state, and local laboratories into a network that can respond to emergencies involving biological, chemical or radiological contamination of food.

FDA also collaborates extensively with foreign governments. In addition to establishing offices overseas, the FDA has a large number of formal agreements and arrangements with its counterparts in different countries, the European Commission, and the World Health Organization, which improve the effectiveness of FDA programs by providing mechanisms for sharing human, scientific, and investigational resources and knowledge and by promoting responsible international standards and regulations. In a new pilot program, the FDA combined resources with the European Union and Australia to conduct inspections of facilities in certain countries that manufacture the starting materials for many drugs that end up in the United States and other countries.

Current approaches to collaboration in HHS are also shown in a number of notable efforts at the Centers for Medicare and Medicaid Services (CMS). CMS increases collaboration through health care industry forums including town hall meetings, open door forums, federal advisory committees, and industry presentations. Business partner collaboration activities include meetings with associations, Medicaid and Medicare Part D user calls and quality alliances and initiatives. CMS also collaborates with other federal and governmental entities via departmental work groups, Medicare program operations, and through the Nationwide Health Information Network. CMS is also active in collaboration on a civil level with participation in human resources, labor relations and other administrative function bodies and panels.

The Centers for Disease Control and Prevention (CDC) have developed innovative approaches to collaboration with external partners. Two examples include PHGrid and HuGENet. PHGrid is a research and development activity that links multiple collaborators in the public, academic, and private sectors to help develop the capabilities of grid computing as they apply to public health. HUGENet is a linkage into a "network of networks" promoting the exchange of research findings in genetic research. This effort is also tied to similar networks in Australia, Europe, and across North America. This allows for scientists to collaborate and share genomic knowledge that can be used to prevent disease and improve health in all stages of life.

At the local level, HHS regional offices play an important role in collaboration. Across the country, the HHS regional offices serve as the gateway through which communities and individual citizens can interact with the Department. For example, the regional offices can play an important role in collaborating with local governments and communities in policy development and the implementation of new HHS programs. They also play a key role in providing and/or coordinating services for citizens, and often serve as the primary point-of-contact for citizen engagement with HHS.



4.3 - HHS Strategic Plan for Participation and Collaboration

In an effort to enhance the ability for HHS employees to identify opportunities to participate in the Open Government initiative, an initial action plan has been developed. With the advancement of Internet tools and the use of other communication technology, HHS is testing, developing, and deploying an array of media, tools, and approaches to communicate with the public. Across HHS, agencies are exploring new approaches to foster participation by the public and promote collaboration across government and with non-governmental organizations. Looking forward in 2010, HHS will deploy a Strategic Plan for Participation and Collaboration, based on four core elements:

1. Founding an HHS “Community of Practice” for Participation and Collaboration

The first step toward progress is enhancing awareness and experience across HHS regarding the use of new technologies and approaches to enhance Open Government. Another aspect of importance in this plan is to provide new venues and opportunities for HHS employees, its partners, and the public to obtain experience and learn from others. To accomplish this, HHS is establishing a “Community of Practice” for Participation and Collaboration. This community of practice will enable HHS Open Government innovators to share experiences, policies, and tools, and will increase dissemination of best practices and knowledge throughout the HHS workforce. The community of practice will focus on activities being developed in actual ‘laboratories’ or other facilities that allow testing in developmental Internet spaces and evaluation of results. The community of practice approach will enable many new concepts and applications of technology to flourish in helping “connect” HHS with the public and its partners.

2. Development of an HHS Workplace Menu of Innovative Tools for Participation and Collaboration

One of the first orders of business for the new HHS “Community of Practice” on Participation and Collaboration is developing a “menu” of tools and techniques would encourage participation and collaboration within and without the HHS community. Within the department, several Operating Divisions have expressed interest in deploying an ideation tool to enhance internal operations and boost employee morale. The menu will list common tools and information resources available that agencies may wish to use in participation and collaboration activities. HHS employees and other members of the community of practice will use this menu to share their experiences and lessons learned from using the tools in the menu. Such a feedback mechanism will ensure that the menu and its content remain dynamic and relevant over time.

3. Evaluation of HHS Participation and Collaboration Efforts

Evaluation of the effectiveness of current and planned participation and collaboration efforts will serve as an important component of HHS’s Open Government Plan. Evaluation efforts will be expected to inform near-term activities such as community of practice discussions and the development of the participation and collaboration tools menu, as well as future strategic planning efforts regarding the use of participation/ collaboration activities across HHS.



The evaluation activities will focus on three broad components: 1) evaluation of the effectiveness of the methods/techniques utilized in a sampling of featured HHS participation and collaboration activities (we will aim to select a diverse sample of initiatives so that we can evaluate not only the technical tools and management approaches applied to the use of these tools, but also the settings or issues for which participation and collaboration issues are best suited); 2) stakeholder evaluations of the effectiveness of engagement approaches; and 3) an assessment of the effectiveness of the participation and collaboration methods/techniques in supporting agency priorities. With regards to this third component, the evaluation will pay close attention to the extent to which public inputs garnered through participation efforts have contributed to the HHS priorities, as well as any best practices with regards to the handling of and responding to public comments.

4. Addressing Barriers to Participation and Collaboration at HHS

HHS leadership has designated the promotion of innovation across HHS as major priority. In our approach to implementing new ways to work together, HHS has identified barriers that impede new methods of participation and collaboration and is now working to overcome them.

One area that has represented a barrier to participation and collaboration has been the lack of knowledge about what technology platforms and services can be used in the workplace and what privacy and security concerns and protections are involved. HHS is working to inform workers on how to utilize Web 2.0 technologies responsibly and safely and promote their use to promote participation and collaboration activities.

Another source of difficulty impacting working with the public was identified as restrictive policies related to the Paperwork Reduction Act of 1984. Currently, research activities to collect information from the public require many layers of project review to comply with management controls introduced as a consequence of the statute. Now, HHS is working with the Office of Management and Budget to eradicate unnecessary obstructive practices and bureaucracy that will enable more effective and efficient data collection.

An important consideration for the future of communication and deployment of advanced collaboration and participation tools is the informatics infrastructure and technical support in HHS. Being such a large organization, HHS has an array of decentralized information systems, and the interactions among users and movement of important data can be inhibited by lack of connectivity or technical support. HHS is studying options through the Chief Information Officer Council to optimize sharing of experiences and improving connections across information systems. New policies and technical infrastructure will be a target of HHS work in the future to ensure that technology can be used effectively in the workplace.

4.4 - Featured Activities for Participation and Collaboration

In looking to the future, HHS agencies are creating innovative new approaches to participation and collaboration. These approaches are engaging Web 2.0 technologies that include the following functional capabilities:



- Blogging, rating and ranking of ideas, policies, priorities
- Crowdsourcing to identify public opinion and preferences
- Group collaboration tools such as wikis, portals, and file-sharing services
- Idea generation tools
- Use of mobile technologies such as text messaging services
- On-line awards and competitions

Described below are samples of planned HHS activities for 2010 that are engaging innovative new participation and collaboration mechanisms.

Delivery of Consumer Information on Patient Safety and Health

Product Safety Text-Message Pilot

FDA has launched a six-month pilot to assess the use of text messages as a channel for reaching healthcare professionals, patients, and other members of the public. Once participants subscribe to the pilot, they will receive real-time MedWatch text message alerts on topics of interest they select. The content of the text messages will consist of alerts that provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. The alerts contain actionable information that may affect both treatment and diagnostic choices for healthcare professional and patient. To assess impact and user experience, after six weeks have passed, and then four months, the participants will receive a text message with a link to a survey.

The Text4baby program

Text4baby is an innovative mobile information service designed to promote maternal and child health. Through Text4baby, pregnant women and new moms receive timely health information via free mobile/cell phone text messages. This service was made possible through a broad private-public partnership that includes government, businesses, professional organizations, academic institutions, and non-profit organizations. A comprehensive list of partners can be found at <http://www.text4baby.org/partner.html>. Federal agencies provided input on evidence-based scientific recommendations, health promotion and disease prevention programs, and community health resources available to medically underserved communities and vulnerable populations. Individuals who sign up for the service by texting BABY to 511411 (or BEBE for Spanish) receive three free SMS text messages each week timed to their due date or baby's date of birth. The messages focus on topics critical to the health of moms and babies, including nutrition, seasonal flu prevention and treatment, mental health issues, risks of tobacco use, oral health, immunization schedules, and safe sleep. Text4baby messages also connect women to public clinics and support services for prenatal and infant care. Information provided to mothers through Text4baby can help them take care of their health and give their babies the best possible start in life.



Use of Social Media to Reduce Harm from Tobacco Products

The Food and Drug Administration is planning to increase use of social media tools including widgets, podcasts, YouTube, and other novel avenues to increase awareness of and compliance with the restrictions on advertising and access to cigarette and smokeless tobacco products by youth.

Expanding the Functionality of Personal Health Records

CDC is exploring the use of electronic Personal Health Records (PHR) as a way to 1) distribute health data to individuals who participate in the NHANES in-person survey and 2) deliver personalized CDC health information directly to consumers. A CDC pilot demonstrated that data collected through [NHANES](#) could be provided securely to individual participants through a PHR to augment or replace individual reports sent through the mail. Participants were able to control their personal health information and choose to share their data with others or retract that capability on demand. The pilot demonstrated that data could be linked to health information resources and that NHANES data can be coded using standard methods and populated into a Continuity of Care Record -- making it readable across PHRs and electronic medical records in doctors' offices and hospitals. Additionally, CDC and Microsoft are investigating the potential use of Web 2.0 tools that allow users of Microsoft's PHR platform, HealthVault, to have personally tailored CDC disease management and prevention resources delivered to their PHR to improve informed decision making about their current and future health needs.

User-Friendly Information Services for Health Care Delivery

Using Cell Phone Applications as an Effective Health Care Program Dissemination Tool

The Agency for Healthcare Research and Quality (AHRQ) will be assessing the effectiveness of cell phone applications to increase the dissemination and implementation of effective health care program products among underserved priority populations. This will help overcome mobility barriers and enable access to high value information by users without readily available computers.

Delivering Computerized Geography-based Inventories of Patient Care Services

The Indian Health Service delivers health care services via hundreds of patient care facilities scattered across 35 states. The type of on-site services offered varies significantly place-to-place. A computerized patient portal is being developed to help patients determine which services are available at the nearest site and locations and travel distances to other sites where needed services may be available.

Medical Research Connections and Collaborations for Patient Engagement

Advancing Diabetes Research through Crowdsourcing

Via a Harvard program being pursued in partnership with InnoCentive, HHS is learning about how crowdsourcing and social networking can be harnessed to advance diabetes research.



This approach is helping to generate new research ideas to address complex challenges of living with diabetes and will yield new perspectives on how research is done.

Advancing Health of Women Study

A new resource for public engagement in medical research has been developed through a partnership with the Army of Women and the National Cancer Institute. Through the use of Web 2.0 tools for connectivity and collaboration, women -- with or without breast cancer -- can sign up and respond to a series of periodic secure online questionnaires about their health, family health history, nutrition, and physician activity. This population of women and their data is then connected to the research community via the web. Women can add more information about their health over time, enabling more research questions to be tested. This new model of engagement has the potential to revolutionize how research studies are conducted.

Resources for Public Information Needs about Medical Research

Recently, the public was provided a new information resource by the National Institutes of Health (NIH) called the Research Portfolio On-line Reporting Tools (RePORTER) system, which provides summary information about all biomedical research projects and related activities from NIH and other HHS agencies. In addition to facilitating public participation, RePORTER also provides the basis for more effective collaboration between agencies. In addition to providing a central repository that spans several HHS Operating Divisions engaged in health-related research, RePORTER provides information on research funded by the Veteran's Administration. Components of the Department of Defense and other research agencies also have requested information on the system, increasing the potential for even broader collaboration and coordination.

Technology for Teamwork

Enabling Collaboration among HHS Employees through Enhanced Access to Information Technology

One of the recent advances implemented to help the HHS workforce collaborate across the department involves technical engineering and revisions of management policies that provide HHS employees with improved access to common software programs and tools. The diversity in the types of work at HHS, breadth of the mission, and geographically-dispersed workforce of HHS have over the years led to deployment of multiple information systems in HHS agencies, which created complications for workers who wished to access common software to work on common projects. This problem has now been solved. The net effect of this advance will allow project officers of a cross-agency team to work together via the intranet and overcome geographic, organizational, and resource boundaries that previously slowed progress and limited collaborative work.

Implementing New Electronic Collaboration Platforms for HHS Planning and Evaluation Activities

One of the many ways that new projects are developed and existing ones are improved is through the use of agency planning and evaluation activities. Across HHS, this often means that a broad array of experience and knowledge from across the organization and from the



public is needed. Current approaches to planning and evaluation are limited by the lack of knowing where expertise, data, and information are located throughout the organization. The emergence of electronic technologies to support group document collaboration, expert locator services, crowd-sourcing, wiki functions, and other related activities have brought the potential for new efficiencies in government planning and evaluation. A recent survey conducted at HHS indicates that a small percentage of employees have work experience with these technologies, but are eager to learn more about how to use them to improve their work. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) will be deploying and piloting several new collaboration tools. These will include a wiki tool for collaborative editing, a desktop tool for online conferencing, and an analysis of the organization's suitability for deployment of more comprehensive collaboration tool that would integrate a number of collaborative functions into a single platform. Based on lessons learned from the pilot deployments, ASPE will consider adopting these technologies organization-wide. Lessons learned from deployment in this atmosphere may provide useful lessons for broader deployment across HHS.

Better Healthcare through Better Information

Nationwide Health Information Network – Direct

A key component of the Nation's emerging health information technology infrastructure is the Nationwide Health Information Network (NHIN) – a set of standards, policies, and services that enable the secure exchange of health information over the Internet. "NHIN Direct" is the latest development in the evolution of the NHIN. It's an important effort to develop a "lightweight on-ramp" to the NHIN that will enable simple, direct exchanges of information between providers, labs, pharmacies, and consumers -- and which will be easy to adopt and implement. In a process that launched on March 1, NHIN Direct is being designed in close collaboration with the community of potential users, with the entire process taking place in the open, in public, on a NHIN Direct wikispace. NHIN Direct will then be implemented in real-world tests and deployments by members of the community – with HHS's Office of the National Coordinator for Health Information Technology (ONC) playing a coordinating and convening role. The gist of the NHIN Direct strategy is to utilize a community-driven approach to ramp up and power NHIN Direct-powered health information exchange.

Gathering Public Input on the Rollout of Health Information Technology

In an effort to reach very diverse stakeholder groups, HHS's Office of the National Coordinator for Health Information Technology (ONC) is communicating through a variety of mediums, including encouraging bi-directional communication in a blog format. ONC blog authors provide opinion regarding ONC events and offer a personal perspective on current agency events. Readers are encouraged to leave comments on the blog and are able to rank comments according to favorability, thus helping the ONC communication team identify trends in reader opinion. The ONC blog is syndicated and often re-published on external websites by members of the public.



Finding New Ideas – Innovation in the Work Place

Centers for Medicare and Medicaid Services Plans Electronic Suggestion Box

In a new approach to using employees' experience and know-how to solve complex problems, CMS will be piloting a new electronic employee suggestion box, which will use crowdsourcing, rating and ranking capabilities to identify the best ideas and solutions. The pilot will provide a way for CMS employees to offer unbounded suggestions and ideas relevant to CMS programs and CMS as a place to work. CMS will also ask employees to submit their best ideas for improving specific program or administrative areas.

Substance Abuse and Mental Health Services Administration (SAMHSA) Innovative Employee Engagement Initiative: PeopleFirst

Open government concepts have been applied internally at SAMHSA to improve program management and measurement. SAMHSA has launched an innovative, employee-driven organizational development initiative titled "PeopleFirst." Through a collaborative intranet space and virtual and physical suggestion boxes, employees submit ideas for improvements in both programmatic and administrative domains that are then further explored and worked on by the employees themselves. This multi-faceted initiative is leading to significant gains in operations, level of employee engagement, and overall workforce productivity.

4.5 - Looking Beyond the Horizon

Building a better future for the health and well-being of the nation benefits from getting everyone involved. Harnessing the power of participation and collaboration holds great potential to help us advance our mission. In the months and years ahead, HHS will continue to pursue innovative approaches to doing so, in the spirit of commonwealth and "all hands on deck."



5 - HHS Flagship Initiatives

We are proud of the remarkable work that is being done across HHS to advance Open Government and, in doing so, our mission. We have designated five initiatives in particular as “Flagship Initiatives” that we believe embody an Open HHS:

- The Centers for Medicare and Medicaid (CMS) Dashboard
- The Food and Drug Administration (FDA) Transparency Initiative
- FDA-TRACK
- FOIA Excellence
- The Community Health Data Initiative

5.1 - Centers for Medicare and Medicaid (CMS) Dashboard

- See description in the Transparency section 3.2 of the plan, on page 14

5.2 - Food and Drug Administration (FDA) Transparency Initiative

- See description in the Transparency section 3.2 of the plan, on page 18

5.3 - FDA-TRACK

- See description in the Transparency section 3.2 of the plan, on page 21

5.4 - Excellence in FOIA Administration

- See description in the Transparency section 3.7 of the plan, on page 37

5.5 - Community Health Data Initiative

The Community Health Data Initiative is a major new public-private effort that aims to help Americans understand health and health care performance in their communities -- and to help spark and facilitate action to improve performance.

The fundamental approach being taken by the initiative is to catalyze the advent of a network of community health data suppliers (starting with HHS) and “data appliers” who utilize that data to create applications that (1) raise awareness of community health performance, (2) increase pressure on decision makers to improve performance, and (3) help facilitate and inform action to improve performance.

The approach we’re taking has two parts. First, we will be providing to the public, free of charge and without any intellectual property constraint, a Community Health Data Set harvested from across HHS – a wealth of easily accessible, standardized, structured, downloadable data on health care, health, and determinants of health performance at the



national, state, regional, and county levels, as well as by age, gender, race/ethnicity, and income (where available). This data set will consist of hundreds (ultimately, thousands) of measures of health care quality, cost, access and public health (e.g., obesity rates, smoking rates, etc.), including data produced for the Community Health Status Indicators, County Health Rankings, and State of the USA programs. It will include a major contribution of new national, state, regional, and potentially county-level Medicare prevalence of disease, quality, cost, and utilization data from the Centers for Medicare and Medicaid Services (CMS), never previously published, as well as data for measures tracked by Healthy People 2020. And it will include information on evidence-based programs and policies that have successfully improved community performance across many of these measures. While the initial Community Health Data Set is a set of data files downloadable from a webpage, we will be deploying a new data warehouse and web portal to deliver it with maximum efficiency (including exposing the data via a web service) by the end of 2010. The data warehouse and portal are currently under development at the National Center for Health Statistics.

Second, working with a growing array of technology companies, researchers, health advocates, employers, media, consumer advocates, marketers, providers, etc., we are seeking to identify the uses of this data that would do the most to raise awareness of health performance, help motivate civic leaders and citizens to improve performance, and help improvers do the improving. Potential examples include:

- Interactive health maps on the web that allow citizens to understand health performance in their area vs. others with tremendous ease and clarity
- “Dashboards” that enable mayors and other civic leaders to track and publicize local health performance and issues
- Social networking applications that allow health improvement leaders to connect with each other, compare performance, share best practices, and challenge each other
- Competitions regarding how communities can innovate to improve health performance
- Viral online games that help educate people about community health
- Utilization of community health data to help improve the usefulness of results delivered by web search engines when people do health-related searches and further raise awareness of community health performance
- Integration of community health-related data into new venues, such as real estate websites, which could be highly effective disseminators of such information
- Etc.

Through this dialogue, the public-private Community Health Data Initiative team is recruiting companies, nonprofit organizations, advocacy groups, and innovators of all stripes to utilize the data HHS is providing and develop applications for the public along the lines of the above – and also provide feedback on what data going forward would be most useful for HHS to supply.

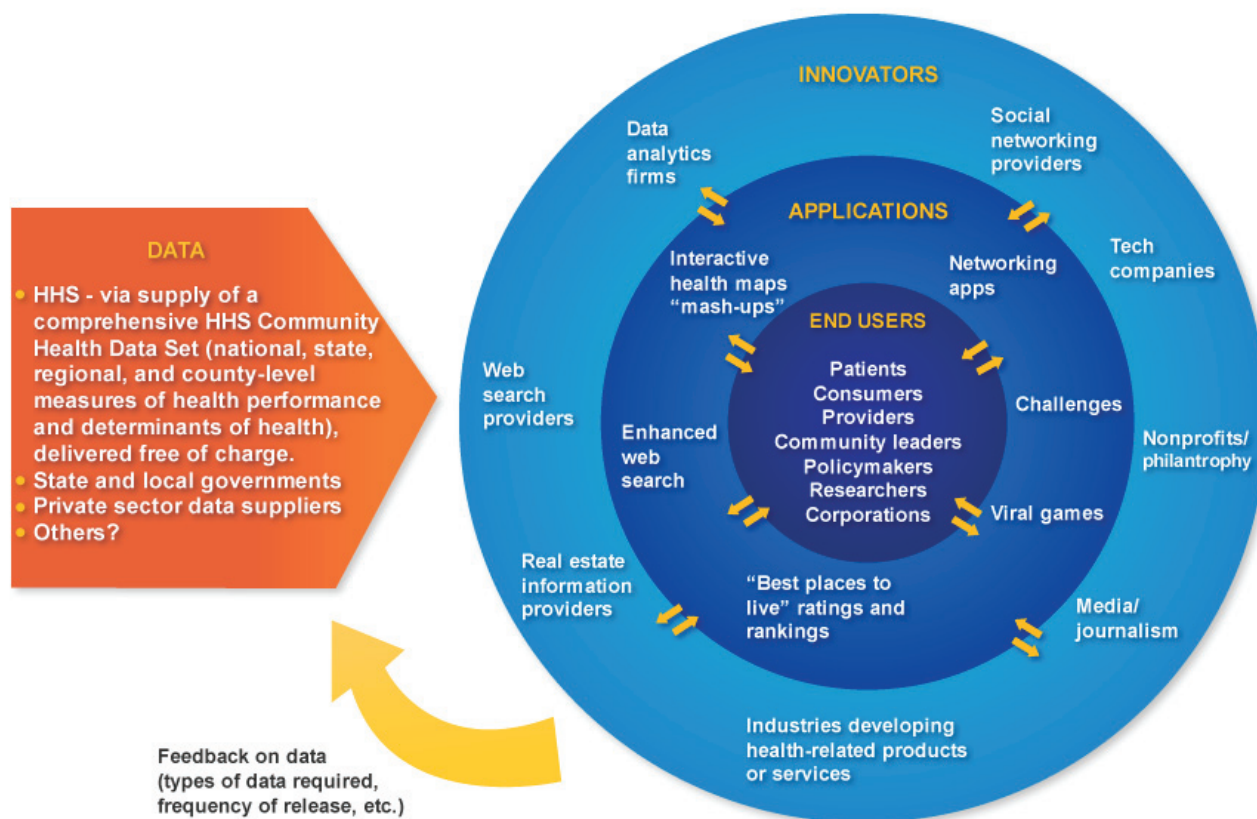


The objective is not only to deploy the HHS Community Health Data Set, but also to trigger the creation and use of an ever-growing array of new applications that increase awareness of community health performance and spark action to improve performance – with the ultimate metric of success being improvement in the very health measures that are being surfaced via the data set.

In sum, the Community Health Data Initiative is working to leverage the power of transparency, participation, and collaboration to improve community health. It's not an initiative owned by any one organization. It's an American initiative, embodying the spirit of commonwealth and which will enable us to do things that can only be done when we all work together.

And it's an initiative for which we also plan to share our core methodologies and program materials with other agencies across the government who have already begun to express interest in replicating this approach in other sectors.

Design Framework for HHS Community Health Data Initiative





Conclusion

We at HHS are excited about the power of Open Government to help advance our ability to improve the health and well-being of the American people. As described by this plan, we will be making significant strides toward a more transparent, participatory, and collaborative HHS in the months to come. But we also recognize that this plan represents just the beginning of a continuing journey – a journey toward a more open and effective HHS.

It's a journey that will be powered by a growing number of Open Government thinkers and doers at all levels and across all divisions of HHS – most notably, the people who are driving the wide array of inspiring initiatives described in this plan.

It's a journey that will be powered by an expanding dialogue across HHS and with the public on Open Government and the ways in which its power can be harnessed.

It's a journey on which we have an enormous amount to learn – and will be seeking to share those learnings across HHS and the government.

And it's a journey that we believe will pay great dividends in terms of our ability to serve the American people. We very much look forward to it, and to continuing input and help from all who care about the advancement of the health and well-being of the nation.